UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

THE UNITED STATES OF AMERICA; and

THE STATES OF CALIFORNIA, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MICHIGAN, NEVADA, NEW HAMPSHIRE, NEW MEXICO, NEW YORK, TENNESSEE, and TEXAS; and

THE COMMONWEALTHS OF MASSACHUSETTS and VIRGINIA; and

THE DISTRICT OF COLUMBIA;

ex rel. JANE DOE AND MARY DOE,

Plaintiffs,

v.

PDL BIOPHARMA, INC., and ESP PHARMA HOLDING COMPANY, INC.,

Defendants.

CIVIL ACTION NO.

07-3263
(Townes, J.)

FILED IN CAMERA and UNDER SEAL

FALSE CLAIMS ACT *QUI TAM* COMPLAINT

FIRST AMENDED COMPLAINT

INTRODUCTORY STATEMENT

1. This is an action brought on behalf of the United States of America by Plaintiffs JANE DOE AND MARY DOE (hereafter referred to as "Relators") against Defendants pursuant to the *Qui Tam* provisions of the Federal Civil False Claims Act, 31 U.S.C. §§ 3729-33 ("Federal FCA" or "FCA"), and on behalf of the above-named States under their respective State False Claims Acts ("State FCAs") (together referred to herein as "*Qui Tam* Action"). Pursuant to 31

U.S.C. § 3730(b)(2), and comparable provisions in the State FCAs, this action is brought *in camera* and under seal.

2. The Relators in this case are employees of Defendant PDL BioPharma. The allegations of this Complaint arise from the Relators' independent, unique and first-hand knowledge of the unlawful practices of the Defendants with respect to three drugs:

(a) **IV Busulfex® (busulfan)(Black Box warning),** a prescription drug approved February 4, 1999 under the Orphan Drug Act, 21 U.S.C. sections 360aa-360dd, for the treatment (in combination with cyclophosphamide and given as an every-6-hour infusion) as a conditioning regimen prior to allogeneic hematopoietic progenitor cell transplantation ("HSCT"), i.e. bone marrow transplant, for Chronic Myelogenous Leukemia ("CML"). This drug was developed and first manufactured and marketed by Orphan Medical, Inc. Defendant ESP Pharma Holding Company, Inc. acquired worldwide rights to Busulfex from Orphan Medical, Inc. in or about 2002-2003. Defendant PDL BioPharma acquired the drug and the sales force, etc. when it acquired Defendant ESP Pharma in about March 2005;

(b) **Cardene IV® (nicardipine),** a prescription drug approved January 30, 1992 for the *short-term* treatment of hypertension when oral therapy is not feasible or not desirable. Cardene was acquired by Defendant ESP from Wyeth in 2002, and was marketed by ESP until 2005 when ESP and all rights to Cardene were acquired by Defendant PDL; and

(c) **Retavase® (reteplase),** a prescription drug approved in October 1996 for use in the management of acute myocardial infarction ("AMI") in adults for the improvement of ventricular function following AMI, the reduction of the incidence of congestive heart failure, and the reduction of mortality associated with AMI. In 2005, Defendants PDL and ESP Pharma acquired exclusive rights to this drug from Centocor, Inc., a wholly owned subsidiary and

biopharmaceutical operating company of Johnson & Johnson, Inc.

3. The Defendants in this case have violated several laws, including without limitation, the Federal and State FCAs, the Medicare and Medicaid Anti-Kickback Act, and the Federal Food, Drug, and Cosmetic Act, by engaging in numerous unlawful activities in their marketing and other activities in connection with these three drugs from at least 2002 through the present and continuing. The Defendants' unlawful activities involve various means of providing financial benefits and/or incentives to their customers (*e.g.*, physicians, clinics, hospitals, transplant centers, long term care facilities) and others in order to induce them to promote, purchase and/or use one or more of the drugs at issue including, without limitation:

(1) offering and paying "kickbacks" in various forms to physicians and others as an inducement and/or reward for their prescribing or promoting of the drug, including for off-label purposes; and

(2) "off-label" marketing of the drugs for unapproved indications and/or dosing regimens in order to cause the drug(s) to be prescribed instead of competing drugs.

4. The purpose of these unlawful activities is and has been to gain market share for each drug over its competitor drug(s) and to increase reimbursement for such drug from governmental (and private) health insurance programs. Defendants' actions and omissions have caused improper and illegal billings to the federal government and to the state governments named herein. All of the foregoing unlawful practices are detailed in the pages below, and also in Relators' Disclosures served on (or otherwise made available to) the federal and state Plaintiffs in this matter.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action under the Federal FCA pursuant to 28 U.S.C. §§ 1331 and 1345, and 31 U.S.C. §§ 3732(a) and 3730, and has supplemental jurisdiction over the State FCA claims pursuant to 28 U.S.C. § 1367.

6. Venue is appropriate as to the Defendants in that the Defendants transact business in this judicial district, and acts proscribed by 31 U.S.C. § 3729 have been committed by the Defendants in this judicial district. Therefore, venue is proper within the meaning of 28 U.S.C. § 1391(b) & (c), and 31 U.S.C. § 3732(a).

7. To Relators' knowledge, jurisdiction over this action is not barred by 31 U.S.C. § 3730(e): there is no civil suit or administrative proceeding involving the allegations and transactions herein to which the United States is a party; there has been no "public disclosure" of these allegations or transactions; and Relators are "original sources" of the information upon which these allegations are based.

THE PARTIES

8. Relators Jane Doe and Mary Doe are citizens of the United States of America and current employees of Defendant PDL. Together they bring this *Qui Tam* action based upon direct and unique information obtained as a result of their employment at PDL. Relators' identities and employment information are provided in the Disclosure Statement being produced to the United States and to the Plaintiff States pursuant to the Federal and State FCAs.

9. Defendant PDL BioPharma, Inc. ("PDL"), previously known as Protein Design Labs, Inc., is by its own description:

> "a biopharmaceutical company focused on discovering, developing and commercializing innovative therapies for severe or life-threatening illnesses. Commercially focused in the

acute-care hospital setting, PDL markets and sells its portfolio of commercial products in the United States and Canada. A pioneer of antibody humanization technology, PDL promotes this technology through licensing agreements and clinical development of its own diverse pipeline of investigational compounds. PDL's research platform centers on the discovery and development of antibodies to treat cancer and autoimmune diseases." See www.pdl.com. PDL is traded on the NASDAQ under the ticker symbol "PDLI." It conducts business throughout the United States and in Canada and Europe.

10. Defendant PDL's headquarters and its research and development activities are located in Fremont, California (soon to be moved to Redwood City), but its commercial products office, including sales, marketing and clinical affairs, is located in Edison, New Jersey (where Defendant ESP, acquired by PDL in 2005, was headquartered). PDL acquired the rights to market IV Busulfex®, Cardene® IV, and Retavase® when it acquired Defendant ESP Pharma in 2005.

11. Defendant ESP Pharma Holding Company, Inc. (ESP Pharma), is currently a wholly owned subsidiary of Defendant PDL. ESP Pharma, based in Edison, New Jersey, was founded in April 2002 around the acquisition of several therapeutics from Wyeth, including what became ESP Pharma's leading product, Cardene® IV. ESP was a leading privately held, hospital-focused pharmaceutical company focused on selectively acquiring approved and late-stage development products addressing the needs of the acute-care hospital market. ESP Pharma acquired worldwide rights to Busulfex from Orphan Medical, Inc. in or about 2003, and Defendant PDL BioPharma acquired the drug and the sales force, etc. when it acquired Defendant ESP Pharma in March 2005. With the acquisition of ESP in 2005, PDL also acquired certain product rights and assets relating to Retavase® from Centocor, Inc., a biopharmaceutical

operating company of Johnson & Johnson (Centocor). These included the rights to manufacture, develop, market and distribute Retavase® (reteplase) in the United States and Canada.

FEDERAL AND STATE LAWS

Government Health Insurance Programs

12. The Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.*, (hereinafter "Medicare"), is a Health Insurance Program administered by the Government of the United States that is funded by taxpayer revenue. The program is overseen by the United States Department of Health and Human Services. Medicare was designed to be a health insurance program and to provide for the payment of hospital services, medical services and durable medical equipment to persons over sixty-five (65) years of age and others that qualify under the terms and conditions of the Medicare Program. Payments made under the Medicare Program include payment for certain prescription drugs used during treatment at an appropriate medical facility and otherwise, as well as certain injectable drugs. Pursuant to the Medicare Prescription Drug Improvement and Modernization Act of 2003, effective January 1, 2006, Medicare Part D took effect, extending prescription drug coverage to all Medicare eligible persons who choose to participate in Part D.

13. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (hereafter "Medicaid"), is a Health Insurance Program administered by the Government of the United States and the various individual States and is funded by State and Federal taxpayer revenue. The Medicaid Program is overseen by the United States Department of Health and Human Services. Medicaid was designed to assist participating states in providing medical

services, durable medical equipment and prescription drugs to financially needy individuals that qualify for Medicaid.

14. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") (now known as "TRICARE"), 10 U.S.C. §§ 1071-1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired and deceased members. The program is administered by the Department of Defense and funded by the Federal Government. CHAMPUS pays for, among other items and services, prescription drugs for its beneficiaries.

15. The federal government, including through its Departments of Defense and Veterans Affairs, maintains and operates medical facilities including hospitals, and receives and uses federal funds to purchase prescription drugs for patients treated at such facilities and otherwise. In addition, under the Public Health Service Act, the Section 340B Drug Pricing Program, and the Veterans Health Care Act of 1992, the federal government directly or indirectly provides funds to certain other federal agencies and to state and local facilities and programs, including to non-profit disproportionate share hospitals ("DSH"). *See generally* 38 U.S.C. § 8126.

16. The Federal Employees Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, prescription drugs for its beneficiaries. (Together these programs described in paragraphs 12-16, and any other government funded healthcare programs, shall be referred to as "Federal Health Care Programs" or "Government Health Care Programs").

The Federal Food, Drug and Cosmetic Act

17. The Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 301, *et seq.*, prohibits the distribution of new pharmaceutical drugs in interstate commerce unless the Food and Drug Administration ("FDA") has determined that the drug is safe and effective for its intended use, 21 U.S.C. § 355 (a) and (d), or has approved the drug under The Orphan Drug Act, 21 U.S.C. sections 360aa-360dd. An approved drug may be prescribed by doctors for uses other than those approved by the FDA, but manufacturers are prohibited from marketing or promoting the drug for such unapproved or "off-label" uses. 21 U.S.C. § 331(d). If the manufacturer intends to promote the drug for a new unapproved use, an application for the proposed new use must be filed with the FDA (or an exemption therefrom must be obtained) and any promotional materials concerning unapproved uses must meet strict statutory and regulatory requirements. *See* 21 U.S.C. §§ 360aaa, *et seq*. False statements by a manufacturer or regarding the off-label indications of a drug can also cause that drug to be "misbranded."

18. Whether a drug is FDA-approved for a particular use is an important, and sometimes determinative, factor in whether a prescription of the drug is eligible for reimbursement under many, if not all, Government Health Insurance Programs, including Medicaid. The ODA, 21 U.S.C. sections 360aa-360dd, provides incentives to drug manufacturers to research treatment for diseases and medical conditions that affect a relatively small number of people in the United States, generally under 200,000 individuals. Under the ODA, the FDA is required to grant orphan drug status to a drug if the sponsor shows a "medically plausible basis for expecting the drug to be effective in the prevention, diagnosis, or treatment of that disease or condition." 21 C.F.R. section 316.25(a)(2). *However*, the fact that a

drug has been designated as an orphan drug by the FDA under the ODA does *not* mean that the drug is FDA approved for the treatment of that indication *or* that it is medically accepted for the treatment of that indication, and does not in and of itself support, e.g., Medicare coverage or reimbursement.

19. The FFDCA provides criminal penalties for the dissemination of written information to health care providers regarding the safety, effectiveness, or benefit of the use of a drug that is not described in the FDA approved labeling of the drug, if that written information fails to conform to the law's requirements. 21 U.S.C. §§ 331(z), 333(a)(1)-(2), 360aaa. A manufacturer may disseminate information on a new use of a drug only if it meets the specific requirements set forth in 21 U.S.C. § 360aaa. One of those requirements is that a manufacturer may disseminate written information on a new use of a drug only if the information is about a clinical investigation with respect to the drug and is contained in an article published in a scientific or medical journal, which is peer-reviewed by experts, or in a reference publication. 21 U.S.C. §360aaa-1 states in part:

> (a) Authorized information – A manufacturer may disseminate information under section 360aaa of this title on a new use only if the information –
>
> (1) is in the form of an unabridged –
>
> (A) reprint or copy of an article, peer-reviewed by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device involved, which were published in a scientific or medical journal (as defined in section 360aaa-5(5) of this title), which is about a clinical investigation with respect to the drug or device, and which would be considered to be scientifically sound by such experts; or
>
> (B) reference publication, described in subsection (b) of this section that includes information about a clinical investigation with respect to the drug or device that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device that is the subject of such a clinical investigation . . . .

The Federal and State False Claims Acts

20. The Federal FCA, 31 U.S.C. § 3729(a)(1), makes "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment, a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September 29, 1999.

21. The Federal FCA, 31 U.S.C. § 3729(a)(2), makes "knowingly" making, using, or causing to be used or made, a false record or statement to get a false or fraudulent claim paid or approved by the Government, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September 29, 1999.

22. The Federal FCA, 31 U.S.C. § 3729(a)(3), makes any person, who conspires to defraud the United States by getting a false or fraudulent claim allowed or paid, liable for three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September 29, 1999.

23. The Federal FCA, 31 U.S.C. § 3729(a)(7), makes it illegal for any person to "knowingly" make, use or cause to be made or used a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the Government, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,500 and $11,000 per claim for claims made on or after September 29, 1999.

24. The Federal FCA defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested.

25. As set forth below, several states have passed False Claims Act legislation, which in most instances closely tracks the Federal FCA: California False Claims Act, Cal. Gov't Code § 12650 *et seq.*, Delaware False Claims and Reporting Act, Del. Code Ann. Tit. 6, §§ 1201 *et seq.*, District of Columbia Procurement Reform Amendment Act, D.C. Code §§ 2-308.13 *et seq.*, Florida False Claims Act, Fla. Stat. §§ 68.081 *et seq.*, Official Code of Georgia Annotated, 49-4-168, *et seq.*, Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 *et seq.*, Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/1 *et seq.*, Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5, Louisiana Medical Assistance Programs Integrity Law, 46 La. Rev. Stat. c. 3, § 437.1 *et seq.*, Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, §§ 5A *et seq.*, Michigan Medicaid False Claims Act, MI ST Ch. 400, Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 *et seq.*, New Hampshire False Claims Act, N.H. RSA §§ 167:61-b, *et seq.*, New Mexico Medicaid False Claims Act, 2004 New Mexico Laws Ch. 49 (H.B. 468), 2007 New York Laws 58, section 39, Art. XIII, §189, *et seq.*, Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq.*, Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code §§ 36.001 *et seq.*, and Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 *et seq.* These State False Claims Acts apply, *inter alia,* to the state portion of Medicaid fraud losses caused by false Medicaid claims to the jointly federal-state funded Medicaid program. Each of the statutes listed above contains ***qui tam*** provisions governing, *inter*

alia, a Relators' right to claim a share of the State's recovery.

The Medicare and Medicaid Anti-Kickback Act

26. The Medicare and Medicaid Anti-Kickback Act ("AKA"), 42 U.S.C. § 1320a-7b (b), makes it illegal to offer, pay, receive, or solicit any remuneration, kickback, bribe, or rebate, whether directly or indirectly, overtly or covertly, in cash or in kind, to or from any person in order to induce such person to purchase, lease, or order, or to arrange for or recommend the purchasing, leasing, or ordering of any good, service, or item for which payment may be made in whole or in part under a Government Health Care Program. The AKA not only prohibits outright bribes and rebate schemes, but it also prohibits any payment by a drug company to a doctor if any one of the purposes of the payment is to induce the physician to write additional prescriptions for the company's drug(s). The AKA prohibits such activities in order to secure proper medical treatment and referrals, and to limit the possibility of a patient having to undergo unnecessary treatments or having to accept specific items or services which are based not on the needs of the patient, but on the incentives given to others, thereby limiting the patient's right to choose proper medical care and services. Many States have similar anti-kickback laws governing the irrespective Medicaid programs.

Department of Health and Human Services Office of Inspector General Guidelines

27. As noted above, under the Anti-Kickback Act, it is illegal, *inter alia*, to offer or pay, receive or solicit any remuneration, kickback, bribe, or rebate, in cash or in kind, directly or indirectly, overtly or covertly, to induce such person to order, arrange for or recommend the purchasing or ordering of any good, service, or item for which payment may be made in whole

practices prompted the Inspector General of the Department of Health and Human Services ("OIG" or "HHS OIG") to issue a Special Fraud Alert in 1994, *see* 59 Fed. Reg. 65,376 (Dec. 19, 1994), and further guidance in May 2003. *See* the "OIG Compliance Program Guidance for Pharmaceutical Manufacturers," 68 Fed. Reg. 23731 (May 5, 2003) (the "OIG Guidelines"). Defendant PDL is headquartered in California. The State of California has adopted both the OIG Guidelines and the pharmaceutical industry's own guidelines as law.

Laws Governing Clinical Investigations of Investigational New Drugs

28. The FDA has published regulations governing the use of investigational new drugs, and the conduct of clinical investigations of such drugs. *See* 21 C.F. R. Part 312. An "investigational new drug" includes not only a drug that is not approved, but also includes a drug that is already approved for some use by the FDA, but is being investigated for a new as yet unapproved use, i.e. one that is off-label. *Id.* These regulations govern, *inter alia*, who may be an investigator and/or sponsor, promotion and charging for the investigational drugs, study design and approval, and conduct of any such study. Generally, a sponsor such as a pharmaceutical company: shall not charge the investigator for the investigational drug without the prior written approval of the FDA; and shall not "present in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug." 21 C.F.R. section 312.7.

FACTS AND ALLEGATIONS

29. Relators have been employed by Defendant PDL. Through their employment, they have acquired direct, unique and first hand information about the sales, marketing, clinical affairs and regulatory aspects of the Defendants' commercial business.

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or in part under a Government Health Care Program. Concerns about improper drug marketing practices prompted the Inspector General of the Department of Health and Human Services ("OIG" or "HHS OIG") to issue a Special Fraud Alert in 1994, *see* 59 Fed. Reg. 65,376 (Dec. 19, 1994), and further guidance in May 2003. *See* the "OIG Compliance Program Guidance for Pharmaceutical Manufacturers," 68 Fed. Reg. 23731 (May 5, 2003) (the "OIG Guidelines"). Defendant PDL is headquartered in California. The State of California has adopted both the OIG Guidelines and the pharmaceutical industry's own guidelines as law.

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FACTS AND ALLEGATIONS

29. Relators have been employed by Defendant PDL. Through their employment, they have acquired direct, unique and first hand information about the sales, marketing, clinical affairs and regulatory aspects of the Defendants' commercial business.

30. PDL's sales and marketing of the drugs is coordinated and overseen from Defendants' corporate headquarters in California, but the sales, marketing and clinical affairs activities of the company are generated out of the commercial products office in New Jersey. ESP Pharma employed numerous "sales reps" throughout the United States to market Busulfex, Cardene, and Retavese, and the sales and marketing and other relevant staff were acquired by PDL in 2005 when it acquired ESP. At Defendant ESP, and continuing for about the first year after Defendant PDL acquired ESP, the cardiovascular team sold all three drugs at issue in this case. Currently, the Sales force is divided into 2 teams – Oncology (Busulfex) and Cardiovascular (Cardene & Retavase). In the U.S., there are currently 3 sales persons for Oncology; two of these three were also with ESP, as part of Medical Affairs, and were there selling at the time ESP acquired Busulfex from Orphan and sales increased dramatically. There currently are about 130 sales persons for Cardiovascular products. Each of these three drugs/commercial products has its own Marketing team: i.e., there is a separate marketing team for each of Busulfex, Cardene and Retavase.

31. In addition to the Sales and Marketing force, PDL has about 11-12 medical science liaisons ("MSLs") whose job is supposed to "professionally and ethically establish, cultivate and maintain long-term relationships with influential members of the medical community within a specific geographic area; identify and support advocates in disease states in which the company has interest; and promote awareness of medical/scientific developments and issues related to disease states of company interest and company products. Key functions will also include facilitating various company educational initiatives and fostering research collaborations with leading academic researchers." See current PDL BioPharma job posting.

32. Each MSL has a geographic territory, certain hospital accounts, and certain types of

drugs within his or her responsibility. For example, one MSL would cover Cardene and Retavase in the states of North Dakota, South Dakota, Nebraska, Minnesota, Iowa, Missouri, Illinois, and Wisconsin. An MSL may also at times cover all or parts of another territory, as staffing needs require.

33. Relators traveled around the country, attended trainings and meetings, and communicated extensively with their colleagues around the United States, and as a result are very familiar with the national practices of PDL with respect to the three drugs at issue in this case.

The Three Drugs: IV Busulfex® (Black Box), Cardene IV®, and Retavase®

34. Relators allege that the Defendants have engaged in misconduct with respect to the following three drugs already described in part above. A large part of PDL's revenues come from Government Health Care Programs according to information Relators have received during their employment.

IV Busulfex® (busulfan) (Black Box warning)

35. IV Busulfex, an alkylating agent, is a prescription drug "approved" by the FDA on February 4, 1999 under the Orphan Drug Act, *supra*, IV Busulfex has been designated as an orphan drug *only for* the "Use in combination with cyclophoshamide as conditioning regimen prior to allogeneic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia." In other words, it is approved only for the treatment (in combination with cyclophosphamide and given as an every-6-hour infusion) as a conditioning regimen prior to *allogeneic* [i.e. matched or mismatched donor] hematopoietic progenitor cell transplantation ("HSCT"), i.e. bone marrow/stem cell transplant, for Chronic Myelogenous Leukemia ("CML"). Although not explicitly approved for use in pediatric patients, dosing adjustment

recommendations are included in the package insert under "special populations." Most use of Busulfex is inpatient, in hospital based transplant centers; outpatient use of Busulfex for transplant is still uncommon, and most outpatient use is off-label (i.e. because it is once daily administration and typically not in combination with cyclophosphamide for transplant in CML).

36. Safety and efficacy have *not* been established, and IV Busulfex® is not approved for other uses, or in dosages or regimens different from those noted in the label. Indeed, in the spring of 2007, PDL unsuccessfully attempted to gain approval from the FDA to expand the label into myeloid leukemias (acute myeloid leukemia or AML and myelodysplastic syndrome or MDS) and expanded dosing/concomitant therapy including once daily dosing (aka QD) and combination with fludarabine. The FDA denied PDL's submission, citing the need for Phase III randomized trials.

37. The on label use of IV Busulfex has been threatened since the introduction of the drug Gleevec (Imatinib) in May 2001. Since Gleevec was approved for the treatment of patients with Philadelphia chromosome-positive CML, such patients no longer routinely receive HSCT as first line therapy. Over the past five-six years, most transplant centers in the U.S. have seen a fifty to sixty percent reduction in the number of transplants for chronic phase CML because patients have opted for initial Gleevec treatment rather than a stem cell transplant. In addition, total body irradiation has become the therapy of choice in some top transplant centers, and now accounts for 20% of all transplants.

38. Despite a continuing decrease in transplants for CML, and no expansion of the on label approved use of Busulfex, U.S. revenue from Busulfex has increased dramatically: from about $5.3 million in 2002, to about $8.1 million in 2003, to $9.7 million in 2004, to about $17.6 million in 2005, to about $19.4 million in 2006. U.S. sales goals for 2007 are $22.38 million,

which is a 15% increase over 2006, with a five-year sales forecast of $26.1 million in U.S. sales in 2011. First quarter 2007 U.S. sales are already *23%* over first quarter 2006. Total Busulfex revenues since it was launched in 1999 through 2007 likely will total over $93 million.

39. Relators estimate that about 95% of these sales (at least in the last few years) are from off-label uses. According to the Defendants' own materials, only 45% of all HSCT in the U.S. is allogeneic [matched or mismatched donor] which is what Busulfex is approved for, as opposed to 55% autologous [self as donor] for which it is *not* approved. Furthermore, CML, the only approved indication for IV Busulfex, now accounts for only 5% of *all* HSCTs performed. Off-label uses account for the rest, including multiple myeloma ("MM"), acute myeloid leukemia ("AML"), myelodysplastic syndrome ("MDS"), non-Hodgkin's lymphoma ("NHL"), Hodgkin's disease ("HD"), and neuroblastoma, other cancers, and certain non-malignant diseases. In addition, a non approved combination, IV Busulfex/fludarabine ("Bu/Flu") now accounts for about 29% of the IV Busulfex usage in 2004 and, on information and belief, is even higher now, and the Defendants are promoting once daily dosing regimen (instead of every 6 hours as indicated). The Defendants' 2007 "core strategy" includes dominating the allogeneic HSCT market and expanding into the *autologous* HSCT market.

40. Most use of IV Busulfex is inpatient, in hospital based transplant centers; about 100 or so transplant centers are the biggest customers/users of this drug. As noted above, outpatient use of Busulfex for transplant is still uncommon, and most outpatient use would be off-label. On information and belief, inpatient use of IV Busulfex is reimbursed through Medicare Part A as part of a bundled procedure (i.e. through diagnostic-related group(s) or "DRGs"). Busulfex recently received a Medicare J-code for separate reimbursement in an outpatient setting (although, as noted, outpatient use for transplant is still uncommon and in most cases, off-label).

IV Busulfex is on the Veterans Administration formulary, and is presumed to be on many private formularies (i.e. as may affect claims under the FEHBP). While outpatient HCST transplants are uncommon, it is a growing area which is often preferred by patients and offers cost savings for the transplant center. IV Busulfex given every 6 hours (as indicated) is not particularly attractive for use in the outpatient setting, however, because its use/dosing is too frequent to be convenient for nurses and patients. However, *off-label* once daily dosing of IV Busulfex, also known as QD, lends itself perfectly to outpatient use and the new Medicare J-code also makes IV Busulfex more attractive for the centers because it enables them to bill the drug separately, instead of as part of a bundled procedure. Nevertheless, QD dosing is off-label, and, even if Busulfex were given outpatient, the only approved use is still for allogeneic transplantation for CML (in combination with cyclophosphamide, and given every 6 hours).

41. To be distinguished from IV Busulfex, there is an oral Busulfan that is now a generic drug known as Myleran which is manufactured and sold by GlaxoSmithKline, a competitor to the Defendants. Oral Busulfan has been on the market since the 1950's and is indicated only for the palliative treatment of acute leukemia. Much of the use oral Busulfan, however, is now off-label, as it too has been used as a conditioning regimen. Defendants' strategy includes dominating the oral busulfan market. While oral busulfan was approved for the palliative treatment of leukemia (prior to stem cell transplantation being mainstream), the FDA approval for IV Busulfex (under the Orphan Drug Act) was based on only 4 randomized, controlled clinical trials using *oral* busulfan as a conditioning agent for allogeneic transplantation in mostly CML patients, and only 1 prospective, single-arm, open-label study involving 61 patients receiving IV Busulfex as conditioning for allogeneic transplant in patients with hematologic malignancies. There have been no additional PDL-sponsored trials planned or executed to

evaluate the efficacy and safety of IV Busulfex in off-label patient populations.

42. In addition, there are few randomized controlled trials comparing IV Busulfex-based regimens to others for allogeneic or autologous transplantation. Use of IV Busulfex/busulfan in conditioning regimens has not consistently been demonstrated superior to other regimens in available published literature. Indeed, Busulfex/busulfan has been reported deleterious in some settings: Increased engraftment failures with cord blood transplants; increased association with mortality in Crawley article [Blood 2005, June 1, Vol. 105, Num 11-- 229 patient trial of reduced intensity conditioning in which the authors found that "the use of busulfan in conditioning was associated with inferior survival (P= .01)."] Little data are available on use of IV Busulfex/busulfan-based conditioning in lymphomas.

43. IV Busulfex has until recently been assigned NDC 67286-0053-8 --- 10mL (6mg/mL) in packages of eight ampoules including eight compatible 5 micron syringe filters. This NDC number is being replaced by a new NDC for the new vial form of IV Busulfex; the new one is NDC 67286-0054-8 10mL (6mg/mL) in packages of eight vials.

44. On information and belief, Defendant sells Busulfex Vials for $4648.16 per tray pack, which is wholesale acquisition cost [WAC]. Hospitals will see variations of this price based on their negotiated discount with their wholesalers, and, on information and belief, based on any other arrangements that may exist between PDL and their customers.

45. IV Busulfex was developed and patented by WITNESS A, a physician at MD Anderson in Houston, Texas, who still receives substantial royalties from the sales of the drug and serves as one of Defendant PDL's consultants and key opinion leaders. WITNESS A is actively involved with PDL in decision-making on all aspects of the drug's development and promotion. As noted above, the drug was first manufactured and marketed by Orphan Medical,

but Defendant ESP Pharma Holding Company, Inc. acquired worldwide rights to Busulfex from Orphan in or about June 2003. Defendant PDL BioPharma then acquired the drug and the sales force, etc. when it acquired Defendant ESP Pharma in January 2005.

Cardene IV® (nicardipine)

46. Cardene IV is a prescription drug approved January 30, 1992 for the *short-term* treatment of hypertension when oral therapy is not feasible or not desirable. One of a class of calcium channel blockers, Cardene IV is most often used in neuro patients, i.e. for intracranial hemorrhage ("ICH"), and subarachnoid hemorrhage ("SAH"). It is also used in patients during cardiothoracic or cardiovascular ("CT/CV") surgical procedures, and also potentially in the Emergency Room ("ER"). It has been included in American Heart Association/American Stroke Association (AHA/ASA) guidelines for AIS (acute ischemic stroke) guidelines as a recommended therapy in *limited* circumstances. In a more recent update of these guidelines (2007), Cardene IV has received a newly expanded recommendation to include rtPA (recombinant tissue plasminogen activator; alteplase is the only approved one) eligible patients both pre- and post-treatment. Further, Cardene IV has received a new recommendation for management of spontaneous intracerebral hemorrhage ("ICH") in adults. However, many physicians feel there is a lack of adequate, well-controlled trials supporting the use of Cardene IV in other areas (i.e. the ER). PDL has given numerous "educational grants" to physicians known to have influence over such guidelines and who could help to further PDL's marketing goals. For example, the following doctors who were reviewers involved in the 2007 AHA/ASA guidelines, are believed to have financial ties to PDL:

- For ICH: WITNESS B, disclosed as part of PDL's consultant/speaker's bureau, he/she has frequent (i.e. weekly) dinners with PDL sales staff, etc.

- For stroke: WITNESS C, has no disclosures for PDL, but he has, on information and belief, received money from PDL via participation in advisory boards.
- For stroke: WITNESS D, one of the authors of the 2007 Stroke guidelines, has disclosed research grants from ESP Pharma/PDL for consultant-advisory boards.
- For stroke: WITNESS E, disclosed speaker's bureau honoraria/consultant-advisory board for PDL.

47. Despite these guidelines, safety and efficacy have *not* been established in conditions (i.e. other than short- term) and Cardene IV® is not approved for other uses, *or* in dosages different from those approved in the label.

48. Cardene is used only in the inpatient hospital setting. On information and belief, most if not all reimbursement is through diagnostic-related group(s) ("DRGs"), as part of a bundled procedure, and there are no applicable CPT, HCPCS or APC (J) codes. Approximately 56% of the use is in Medicare, 7% in Medicaid, and 37% in commercial/private payor. IV Cardene is on the formulary of many Medicare prescription drug plans with prior approval; it does not appear to be on the VA formulary. Cardene is available in packages of 10 ampoules of 10 mL as follows: 25 mg (2.5 mg/mL), with assigned NDC 67286-0812-3. On information and belief, PDL sales reps have been instructing physicians/accounts to bill for the maximum DRG in order to offset the cost of using Cardene IV in lieu of a cheaper generic alternative.

49. Revenues from U.S. sales of Cardene are growing rapidly. In the first quarter of 2007 net sales (3 months ended March 31, 2007) were $34.5 million compared to $24.8 million during same time period in 2006 (*a 40% increase*). From 2005-2006 sales jumped 77%, from $62,143,000 in 2005 to $109,689,000 in 2006 Almost 65% of these revenues (or some $121.5 million just in 2005 and 2006) are from Government Health Care Programs. Cardene competes

with many generics and any IV hypertensive drug.

50. Cardene competes with cheaper generics for formulary inclusion at hospitals. Usually there are a lot of restrictions around its use, but each individual hospital develops it own policy regarding the use of this product.

51. Cardene IV was acquired by Defendant ESP from Wyeth in 2002, and was marketed by ESP from then until 2004-2005 when ESP and all rights to Cardene were acquired by Defendant PDL.

Retavase® (reteplase)

52. Retavase is a thrombolytic prescription drug approved in October 1996 for use in the management of acute myocardial infarction ("AMI") (also referred to as segment elevation myocardial infarction or "STEMI") in adults for the improvement of ventricular function following AMI, the reduction of the incidence of congestive heart failure, and the reduction of mortality associated with AMI. In 2005, Defendants PDL and ESP Pharma acquired exclusive rights to this drug from Centocor, Inc., a wholly owned subsidiary and biopharmaceutical operating company of Johnson & Johnson, Inc.

53. Safety and efficacy have *not* been established in other conditions and Retavase® is not approved for other uses, or in dosages different from those approved in the label. Depending on the off-label use, there can be a high risk of harm or a relatively low risk. For example, there is a very high mortality rate with lytics used for stroke and potentially for peripheral arterial disease ("PAD") and pulmonary embolism ("PE") as well.

54. As with the other two drugs discussed above, most, if not all use of the drug is in the hospital setting and reimbursement is, on information and belief, based on DRGs, i.e. as part of a bundled procedure. However, there is a J code for Retavase: J2993.

55. Defendant ESP had two National Drug Code ("NDC") numbers for Retavase® depending on the dosage: Injection, Reteplase, 18.1 mg, NDC 57894-0040-01 Retavase® 2x18.1 mg and NDC 57894-0040-02 Retavase® 18.1. Currently, Defendant PDL has two of its own NDCs for Retavase: Retavase® Kit NDC 67286-0400-1; and Retavase® Half-Kit NDC 67286-0400-2.

56. PDL's Retavase 2007 Marketing plan includes a 10% increase in revenue from 2006 to 2007. The first quarter of 2007 net sales (3 months ended March 31, 2007) are $6.9 million compared to $6.5 million during the same time period in 2006, for a 6% increase. Relators estimate that a substantial portion of these revenues are from Government Health Care Programs. While Retavase revenue declined 6% between 2005 and 2006 (from $32.7 million to $30.8 million), this was due in part to the transition of the drug from Centocor to ESP/PDL. Also, the market for lytic use in AMI has been declining since 2004 (based on historical trends, the market is predicted to decline by 10.5% from $105 million in 2006 to $90 million in 2007).

57. PDL has increased its promotional spending for Retavase by an astounding 282% from 2005 to 2006 (from $96,614 to $368,780). There are some 129 hospital reps, 15 regional business managers, 3 area directors, 6 corporate account managers, and 1 Vice President for the drug. Its primary competitor, TNKase (by Genentech) has an active phase IV development program, with at least 7 company sponsored clinical trials ongoing in areas such as catheter lysis, ischemic stroke, pulmonary embolism and facilitated PCI (percutaneous coronary intervention). In contrast, PDL has *no* company-sponsored trials.

58. On information and belief, Retavase is sold through wholesalers to extensive group purchasing organizations ("GPOs") and Integrated Health Networks ("IHNs") in which hospitals group together to purchase drugs. In the case of Retavase, WAC price is $2412 with a

standard discount of 25% (to $1809) and a high end discount of 36.25% (or a best price of $1538).

The Defendants' Unlawful Practices

59. The Defendants have violated several laws, including without limitation, the Federal and State FCAs, the Medicare and Medicaid Anti-Kickback Act, and the Federal Food, Drug, and Cosmetic Act, by engaging in numerous unlawful activities with respect to these three drugs from at least 2002 (when Defendant ESP acquired Busulfex and Cardene) to date and continuing. The Defendants' unlawful activities involve various means of providing financial benefits and/or incentives to their customers (*e.g.*, physicians, clinics, hospitals, transplant centers) in order to induce them to purchase and use the drugs, and off-label marketing, all as more fully described hereafter.

A. Off-Label Marketing and Promotion

60. While physicians are allowed to prescribe medications "off-label," if deemed medically necessary, it is a violation of the FFDCA for drug companies to market their products "off-label." In violation of that prohibition, Defendants' sales reps and others, with the knowledge and support of management, routinely promoted uses of the drugs that were off-label.

61. Defendants' MSLs were instructed by upper management to act more like sales people by assisting the reps who were trying to convert a customer to the drug. The MSLs were often not allowed to go on independent visits to physicians, but rather MSLs were instructed to accompany sales reps. This was done in order for the sales team to ensure desired messaging about off-label uses was conveyed.

62. When MSLs questioned the propriety of this activity, sales reps, district

managers, regional managers, and marketing representatives would accuse the MSLs of being "compliance police" or "overly concerned with compliance." Retaliatory actions were often taken against those individuals who spoke out. Over the past 4 months, at least 4 members of the MSL organization have resigned, or been forced to resign, as a result of this behavior.

Retavase Off-Label

63. Off-label promotion occurs in the areas of catheter clearance/lysis, deep vein thrombosis ("DVT"), pulmonary artery disease/PAD, pulmonary embolism/PE, and acute ischemic stroke ("AIS"). Indeed, recent slides prepared by PDL show that only 21% of current sales of Retavase come from use in AMI, the *only approved* indication. In other words, about 79% of the use of this drug is off-label. The sales breakdown is as follows:

- Catheter lysis accounts for 34% of current sales
- DVT accounts for 10% of current sales
- PAD accounts for 19% of current sales
- PE accounts for 10% of current sales
- AIS accounts for 4% of current sales
- AMI (the only approved indication) accounts for 21% of sales

64. One of PDL's 2007 marketing strategic imperatives includes retaining 89% of current business (sales) to meet the $55 million 2007 sales target. Considering that only 21% of sales come from an approved indication, retaining market will require continued significant off-label activity.

65. The reps in at least one region (Greater Chicago area) use "homemade" binders discussing off label uses of Cardene and/or Retavase. The sales reps have been instructed to detail using these binders, but not to leave them or any of the materials behind.

66. While common for all of the MSLs, one MSL, in particular, has been asked to join sales rep(s) for dinners in the Buffalo, New York area with interventional radiologists, even though for Retavase use by IRs is off-label (i.e. because generally IRs would be using the drug for catheter lysis). That same MSL was asked by sales rep(s) to attend a lunch in the vascular suite of a New York hospital; the off-label purposes of such visits would be to discuss use of the drug for PAD and DVT.

67. Another time, a regional business manager insisted that a sales rep accompany an MSL on *any* visit to a Key Opinion Leader. This was done even though many of these meetings result from a request for information that is off-label in nature.

IV Busulfex Off-Label

68. Until recently, there have been only 2 sales reps for this product for the entire country, including the 100 or so transplant centers that are the biggest customers/users of this drug. At the time PDL acquired ESP, all sales reps covered all products, including IV Busulfex. Currently, there are three reps, two of whom are the "original" two reps who were formerly part of Medical Affairs with Defendant ESP Pharma; both of those reps have long-standing relationships with transplant Key Opinion Leaders ("KOLs"). Sales reps have been observed to routinely engage in conversations that center around off-label uses/experience with IV Busulfex. As recently as March 2007, sales reps were responsible for all aspects surrounding Investigator Sponsored or Initiated Trials ("ISTs" or "IITs"). As discussed above, Relators estimate that about 95% of IV Busulfex use in the United States is off-label.

69. There has been no proactive, company-sponsored program to develop Busulfex and expand the label. However, in early 2006 the company decided to approach the FDA regarding possible label expansion based solely on publications, many of which were generated as the result of ISTs originally seeded by ESP. As noted above, PDL's attempts in the first half of 2007 to get FDA approval to expand the label/approved indications for IV Busulfex were unsuccessful. At a meeting with the FDA in the spring of 2007, PDL discussed with the FDA expansion of the IV Busulfex label into myeloid leukemias ***and*** expanded dosing/concomitant therapy based on available medical literature, which is predominantly retrospective or single-center data. The letter from the FDA denying approval of PDL's submission, documents the need for Phase III randomized trials.

70. However, PDL still has no plans for PDL-sponsored research to expand the label. Rather, the company intends to continue the longstanding practice/way of doing business which involves proactively soliciting and paying sponsors for studies, "seeding" ISTs, encouraging publication of data and articles on off-label uses, and then using these tactics and the ISTs as a way to get a "foot in the door" to the transplant centers and KOLs so that IV Busulfex will be part of the protocol for the entire institution, and using the doctors and publications as part of Continuing Medical Education that is not independent of the Defendants and that discusses off-label uses. This strategy overlaps with incentives and kickbacks provided to KOLs and others, as discussed in Section B below.

71. Despite the FDA, the Defendants are promoting IV Busulfex (including in the new Vial packaging just launched) off-label not only by disease state but also by dosing regimen and combination, e.g., in combination with fludarabine (known as the Bu/Flu combination or referred to as "reduced intensity regimens") and through daily (as opposed to every 6 hour)

dosing (referred to as "Qday" or "QD"). For example, PDL's "IV Busulfex Publication Planning: Tactical Recommendations 2007" refers to proactive use of publications (not from PDL-sponsored research) to provide scientific support for use of IV Busulfex in off-label areas such as autologous transplantation (lymphoma, multiple myeloma), Bu/Flu, and transplantation involving cord blood, pediatric patients and/or non-malignancies. Per the company's "Busulfex Tactical Summary for 2007," PDL will be funding publication of review articles in off-label areas (e.g., IV Busulfex in Multiple Myeloma and Non-Hodgkin's Lymphoma). MSLs and Clinical Affairs (WITNESS F/WITNESS G/WITNESS H) are used to proactively approach physicians to publish data favorable to IV Busulfex. Grant money is provided through the IST program or via an educational grant.

72. Despite the FDA's position, the Defendants have made it clear that off-label strategies are part of IV Busulfex marketing plans to increase sales. For example, the Commercial Board of Directors meeting slides (April 2007) state that sales goals for IV Busulfex will be achieved by "*increasing dominance of allogeneic* transplant regimens, through *continued control* over the oral busulfan market *and* increasing share to become the therapy of choice for conditioning regimens in allogeneic *and autologous* HSCT". (*Slide 2, CBOD IV Busulfex Marketing 04-26-07v12.ppt*)(emphasis added). As already noted, IV Busulfex is indicated *only in allogeneic transplant for CML*.

73. The marketing team and the previous Medical Director (WITNESS I) have openly stated that PDL's goal for ISTs is to expand into off-label areas and to increase sales. WITNESS I has been observed by MSL team members to proactively approach physicians to solicit their participation in an "IST" (i.e. "seed" ISTs). Company marketing strategies for 2007 show some 24 U.S. active ISTs in "targeted" [i.e. off-label] areas." While Regulatory Affairs (i.e.

WITNESS J) has been admonishing Marketing to eliminate certain language from their written strategies, it is clear from oral communications that the intent is still to drive expansion into off-label areas through ISTs and publication support. Attempts are also being made to expand IV Busulfex into the outpatient setting, where it will rarely be used on-label.

74. The sales and marketing groups, and others within the company, view the MSL team as a tool to expand off-label use of Busulfex. The Commercial Board of Director meeting slides (see above) state that one strategy for meeting 2007 sales goals is to use "focused MSL activity to support scientific development." However, there is no legitimate PDL-sponsored scientific development. All development for Busulfex has been and is through "investigator-initiated" trials ("IITs"—another term for ISTs), as described below.

75. Sales and Marketing activities are not really kept separate from Clinical Affairs within the company. Sales and Marketing have managed Clinical Affairs since its inception. Comments such as "Our MSL sales force" etc have been used often times in front of others. For example, at the June 27, 2007 Busulfex Cycle II POA meeting in Santa Monica, WITNESS K specifically stated "we can't invest millions in marketing Busulfex because more than 95% of its use is off label – that's why we've brought on the MSL's." He/she then referred to the MSL's as the "MSL sales team." Per the MSL Training, May 15, 2007, Fremont, California, the MSL Department Mission Statement includes: "…to proactively seek commercial opportunities for our products that will give us a competitive advantage." (*Hardcopy slide handout from meeting*). MSL training is being coordinated by the sales team.

76. The MSL Team's concerns about off-label promotion by sales fall on deaf ears. For example, at the June 25 – 27, 2007 Busulfex Cycle II POA/Team meeting, concern was expressed that having sales reps calling on transplant MDs who did not see CML patients during

their normal practice could be construed as soliciting off-label discussions (i.e. what is the purpose for sales calling on physicians who specialize in lymphoma treatment/transplant?). WITNESS L (new Busulfex sales member, and former cardiovascular—i.e. Cardene and Retavase sales team member) stated that he/she didn't see a problem with this because the cardiovascular sales reps do this sort of thing all the time.

77. Further, MSLs' concerns regarding PDL's practice of requiring the purchase of PDL drug products by investigators conducting IST's funded by PDL (primarily for purposes of supporting off-label uses) were at best ignored and at worst led to negative sentiments and retaliation once Clinical Affairs, Sales and Marketing became aware that this issue was being raised by the MSL organization.

Cardene IV Off-Label

78. Off-label promoting of Cardene (nicardipine), is shown, for example, by the facts noted above with respect to Retavase (reps who sell that drug also sell Cardene) and the former cardiovascular sales rep who is now selling Busulfex. Among the off-label uses for which Cardene is being promoted is cerebral vasospasm, a common complication following subarachnoid/intracerebral hemorrhage (SAH) that causes significant morbidity and mortality. Other off-label uses include administration of Cardene IV via bolus injections or in higher concentrations (i.e. double or triple, etc). These uses often take place during surgical procedures or in the emergency department. Although Cardene IV has a broad label for treating hypertension, promotion of the use in certain conditions or procedures, such as hypertensive emergencies or cardiothoracic surgery, are felt by many experts as not supported by available clinical data. PDL's marketing efforts, however, target those audiences.

79. In the last several months, there has been concern expressed by third parties, including through the American College of Clinical Pharmacists ("ACCP"), that PDL Cardene sales reps are behaving inappropriately, including by detailing off-label. For example, one rep reportedly was permanently suspended from Christ Medical Center hospital, Oak Lawn, IL for being on patient care floors selling Cardene. Other reps are being criticized for detailing and encouraging emergency doctors and cardiology residents to use Cardene off-label, sometimes in place of cheaper, generic alternatives. For example, one clinical pharmacist expressed the view that despite the detailing done by the PDL rep, Cardene is *not* the standard of care in cardiothoracic surgery (and is very expensive, i.e. $1,000/day). Another PharmD inquired if "other folks" are seeing "an increase, desire use by MD's of nicardipine for hypertensive emergencies and possible intracerebral hemorrhage. One of our ED's is wanting nicardipine in their [P]yxis for the RN to mix and use in an emergent situation. Has anyone done an evaluation of this type of use?" In response, a pharmacy clinical coordinator expressed his view: "Yes, increased use here too…The connection in my case is simple: drug rep walking around the hospital providing lunches in different areas/physician offices = more drug used. I did not do anything yet but soon will perform a DUE [drug utilization evaluation]. My goal is to get rid of it and use Labetalol and nipride…I hope I can."

B. <u>Illegal Incentives/ "Kickbacks"</u>

80. The Defendants have used numerous types of incentives, kickbacks, etc. in attempt to influence physicians and institutions to purchase and use the drugs, to conduct studies and write favorable publications, including on off-label uses, and to speak at Continuing Medical Education ("CME") and other programs (including on off-label uses). The kickbacks/incentives offered include, but are not limited to: expensive entertainment with no educational agenda or

legitimate business purpose, "educational" and research grants, IITs/ISTs, CME, advisory boards, consulting and speaking engagements, research money, ghost writing, contract research organizations ('CROs") to work with researchers/writers in analyzing data and assisting in publications, advice on how to up-code and use the highest reimbursement codes, and, on information and belief, rebates, discounts and/or other pricing/contracting incentives (which may not be reported to the Government Health Care Programs). The following are just a few examples of the illegal incentives/kickbacks of which Relators are aware and/or which have occurred in Defendants' business over the years in question.

1. **Investigator-Initiated or Sponsored Trials (IITs/ISTs)**

81. Defendants use ISTs as a strategy to drive sales, including off-label sales, in connection with all three drugs. The true purpose of the IST program is to funnel research money to key opinion leaders who will use it to a) get product used within a specific institution, b) support marketing strategies in off-label areas through IST publication, and/or c) to provide monetary support for a key advocate. Investigator-sponsored research is supposed to be identified through unsolicited requests from an independent investigator/physician. In many cases, however, the Defendants' sales force and/or others within the Clinical Affairs department, "seed" the studies. In other words, they find and solicit a doctor they think will give favorable results or who they know has favorable experience using the drug (for retrospective data publications) and will publish and promote off-label, and they give that doctor the idea/parameters the Defendants would like to have studied. In addition, the Defendants require that the drug be purchased at the institution's regular price, rather than providing it free of charge, or at cost, as required by CFR 312.7. The vast majority of PDL's ISTs are in off-label areas, particularly for IV Busulfex and Cardene.

82. Prescribing of drugs such as IV Busulfex for HSCT conditioning is largely driven by what protocol is in place at a given transplant center/hospital. ISTs are funded and used by Defendants to get a protocol started at a particular institution. Once an IST-protocol specifying use of IV Busulfex is in place at an institution, all of the transplants covered by the protocol would use IV Busulfex rather than an alternative regimen. PDL provides grant money to the investigator, but does not provide free drug. The institution is required to purchase IV Busulfex, which directly impacts sales revenue.

83. Defendants' 2007 budget and spending for IV Busulfex is $1.6 million; of that, *$1 million (62.5 %) is for ISTs*, another $490,000 (or 30.6%) is for CME, and the rest is for consultants, educational grants and advisory boards. For Cardene, the proposed 2007 budget for Clinical Affairs was $9 million (for CME, ISTs, publications, etc.). Of this, ISTs were expected to account for about 34%, or $2.5 million, up over 100% from $1.2 million in 2006. For Retavase, the Clinical Affairs' budget for 2007 is about $1.8 million, of which about $550,000 is for ISTs.

84. WITNESS A, Busulfex patent holder and physician at MD Anderson, Houston, TX, still receives royalties from sales of Busulfex. He/she routinely is involved in getting off-label IST's started at MD Anderson and other institutions (e.g., Johns Hopkins) to benefit Defendants (and him). For example, he has aggressively stated his/her opinion about how a specific IST should be conducted, expressed in an email, and requesting it just be done the way he and WITNESS I previously discussed.

85. ISTs are used to drive sales, including in off-label areas, with Cardene and Retavase as well. Until very recently, research grant money for Cardene IV was controlled by a single individual (WITNESS M), with little-to-no oversight. WITNESS M often funded seeded ISTs in

order to funnel money to advocates of PDL. For example, WITNESS M authorized research money for WITNESS N for an IST that PDL approached him to do. The study is a Cardene IV pharmacokinetic study designed to provide selling points the sales team could use in competing against clevidipine (Clevelox; The Medicines Company). Clevelox is anticipating approval within about 12 months. However, in addition to soliciting the IST, PDL approved the grant money despite the objections of internal IST review committee members, who recommended that the trial could be done in-house more quickly and for a fraction of the cost. Members of the committee felt the grant was excessive, and further, the IST would not be completed in time to be of benefit to the sales team in counter-detailing against Clevelox. In another instance, involving Retavase, there was a physician, Dr. RS, who had requested "bridge money" for a study he was conducting for which he hoped he would receive government funding. The earlier findings from his study were very positive for Retavase use in facilitated PCI, an off-label use of Retavase. PDL provided interim grant money for this physician to "hold him over" until government funding was secured. Months later, with no government funding secured, and no interim publications or other work to show for the grant, PDL refused to provide further money.

2. Entertainment

86. Expensive entertainment, with no educational agenda or legitimate business purpose, is commonplace. Relators are aware of numerous examples of such entertainment, including dinners.

87. For example, at the American Society of Hematology ("ASH") meeting 12/06, there was a dinner (aka "Wine & Dine") with 18 attendees (including IV Busulfex KOLs) that cost approximately $5000 (including multiple bottles of Opus One wine at about $250/ bottle), or

about $278/person. Following complaints that the cost of the dinner was excessive, the sales team attempted to give the *appearance* of propriety. At another dinner, during the Cancer and Leukemia Group B ("CALGB") meeting in Baltimore in June 2007 (at a restaurant called Kali's Court), WITNESS O, reported that his/her boss (WITNESS P) instructed him/her to add doctor's names to his/her expense reports, even if they did not attend the dinner, if he/she needed to reduce the overall per-person costs of the meal. There are many similar examples on the Cardiovascular side (i.e. Cardene and Retavase) of the business as well. For example, in November 2006, at the American Heart Association, there was a similar expensive dinner in Chicago for doctors, nurses and office staff. That same month, there was also a very expensive Neurocritical Care "wine and dine" at Pazo's in Baltimore.

3. CME /Symposia/Speakers Bureau

88. CME has been a sham, with Defendants influencing agenda, speaker selection, and program/speaker content behind the scenes, and speakers not disclosing their financial relationships with the Defendants. PDL's strategy materials for 2007 state that the purpose of the symposia, CME programs and Speakers Bureau is to have "Nationally and internationally recognized KOLs to discuss appropriate uses of IV Busulfex to improve patient outcomes." *See* Commercial Board of Directors' Meeting April 26, 2007.

89. For example, at the American Society for Blood and Marrow Transplantation ("ASBMT") National Symposium (a.k.a. "Tandem meeting") in February 2007, at Keystone, Colorado, there was a PDL-funded CME program "Current and Future Trends in HSCT: The Impact of Preparative Regimens," that attracted 800 attendees (40% of the total meeting attendees). Data presented at the symposium was almost exclusively about busulfan-based conditioning regimens. Although "sponsored" by a CME vendor (Medical College of

Wisconsin) through an educational grant from PDL, PDL recruited and selected the faculty and topics. The topics focused almost exclusively on Busulfex when, based on the CME objectives, the program should have covered a variety of conditioning regimens. For example, during CALGB 2006, WITNESS F met with a KOL to discuss his/her availability to speak at the CME program on a particular topic. Moreover, PDL employees (WITNESS F and WITNESS I) were present at the pre-symposium slide review with the faculty. Although several members of the faculty were PDL KOLs and had financial dealings with PDL, those relationships were not disclosed in the CME materials.

90. PDL was also instrumental in a National Visiting Professors 2006-2007 CME program series. Curatio CME Institute LLC was the vendor for this CME program, supported by an educational grant from PDL. The program consists of a list of 17 physician faculty (including WITNESS A--original Busulfex patent holder who still receives royalties), and PDL selected the faculty for the programs based on their favorable IV Busulfex experience/data.

91. Forty-five CME talks are targeted for 2007 under this program. Topics for the CME talks are very broad, and include off-label topics such as *autologous* HSCT. Each faculty member puts together their own slides. Although they are supposed to provide Curatio with the slides to review prior to the CME event, this doesn't always happen. Also, faculty often makes last minute changes that don't get to Curatio. However, the experience of at least one doctor shows that when he refused to speak about what the company wanted, he was not included in the CME program.

92. Speakers are paid an honorarium and are reimbursed for their travel. The specific honorarium amount per speaker varies, but Relators believe it is usually around $2000 - $2500. Sales reps frequently provide transportation for the faculty to these programs. Also, it is typical

for a sales rep to provide dinner for the faculty and the "hosting" institution the evening prior to the CME talk (e.g., FHCRC, deLima CME event).

4. Grants, studies, ghost writing, consulting

93. As of May 2007, educational grants were still being solicited and processed by the sales team. For Busulfex, Cardene and Retavase, Defendants routinely have given grants for unrestricted research purposes or for "CME" to the biggest doctors from the biggest institutions, i.e. the KOLs, and the highest prescribers of the drugs, as a "reward" for their loyalty. These grants have been in the range of a few thousand dollars.

94. Even when responsibility for educational grants was moved from sales to Clinical Affairs, the same understanding was still in place. For example, at the MSL Steeprock training held in Fremont, CA, in May 2007, WITNESS Q, made it clear the company only wants educational grant requests submitted from key institutions where the company wishes to support business. Relators have many examples of grants, speaking engagements, etc. Among the many examples Relators have, are the following: paying a CRO to mine data of Dr. A and assist in publication of this off-label Busulfex use; paying a CRO to do a publication on Retavase; ("ADIS") Press (New Zealand) "Drugs" journal articles on Cardene and Retavase paid for via educational grants; and an excessive/inflated educational grant provided to the Emergency Medicine Cardiac Research Education Group ("EMCREG") in about March 2007 in order to get the doctors organizing the CME event into the Defendants' "camp."

95. The EMCREG grant is a particularly egregious example. The grant was approximately $300,000 and was given by PDL to EMCREG in the Spring of 2007 to support a "Hypertension Consensus Panel." PDL was the only sponsor. Grants over $100,000 have to be approved by WITNESS R, so he must have been aware of the grant. This amount of money is

excessive for this type of event, which typically includes about 10 or so experts. The event was held in Naples, FL at the Ritz Carlton Hotel, where rooms were about $700/night. PDL paid for the entire weekend, although only 1 day of work was done.

5. Advisory Boards

96. Advisory Boards are held in fancy locations and involve very little "work." The purpose of the IV Busulfex ad boards is described as follows in Defendants' 2007 strategy materials: "Competitive Intelligence, Understand conditioning regimen rationale and choices of KOLs for allogeneic and autologous HSCT." *See* Commercial Board of Directors' Meeting April 26, 2007. Among the Ad Boards scheduled for 2007 are ones on TBI (designed to target allogeneic HSCT) and ones on multiple myeloma and lymphoma (targeting autologous HSCT).

97. At least until recently, Defendants have not acted on data or feedback received from Advisory Boards. For example, one doctor commented:

> "Yes, agreeing to participate in yet another phase II trial of another conditioning regimen because PDL wants to develop busulfan is a harder sell than saying, we don't know how to do RIC transplants, someone needs to figure this out, let's participate in a randomized study. There has to be a little more interest in developing the best regimen rather than yet another phase 2 study. If you are proposing a study as a lead-in is one way."

WITNESS S from a 2 hour Ad Board held in conjunction with the 2006 Tandem meeting in Honolulu, HI.

6. Pricing Incentives

98. As noted above, at least for Retavase, GPOs and IHNs typically purchase with large discounts. Moreover, in general, an independent "OIG Compliance Assessment" conducted for PDL by Clarkston Consulting in 2006, noted "there was some concern that PDL did not have a defendable pricing structure. *This could lead to challenges in customer service and potentially compliance issues with government pricing given that a large portion of PDLs revenues come*

from the government". (Slide 13, PDL OIG Assessment Findings Draft 20060914.ppt)(emphasis added).

C. Damages to Government Health Care Programs

99. The above described practices by Defendants have caused the submission of false and fraudulent claims to Government Health Care Programs for reimbursement of the drugs, directly or indirectly through DRGs. Claims filed with the Government Health Care Programs have contained false and fraudulent statements and material omissions. Defendants have marketed the drugs in a way that has compromised physicians' independent medical judgment and threatened patient safety through use of kickbacks and off-label promotion. Defendants have made false and fraudulent statements regarding the drugs.

100. As noted above, a large portion of the Defendant's U.S. revenues for the drugs is from Government Health Care Programs. Overall U.S. revenues from the drugs have totaled over $270 million just for the years 2005 and2006, with increases in all drugs' revenues expected/targeted for 2007 and beyond. In the case of Cardene IV, for example, some 65% is from Government Health Care Programs, out of total revenue from 2005-2006 of about $172 million; in other words, almost $112 million has been from such programs. Government Health Care Programs have been damaged significantly because the majority of the patients who use the drugs are Medicare or Medicaid beneficiaries, and the drugs are often prescribed or used in place of lower priced competitors, including generics.

J. Defendant PDL's Unlawful Retaliation

101. Company employees have been expressing their concerns that the appropriate "rules of engagement" regarding the proper role of marketing/sales vs. MSLs were not being followed and regarding the above described conduct such as off-label marketing, misuse of

ISTs/IITs and CME, kickbacks, etc. Among others, concerns have been expressed to and/or discussed with their superiors and with employees in upper management, clinical affairs, regulatory affairs, legal, and human resources.

102. Defendant PDL has retaliated against many of those who have questioned the propriety of Defendants' practices. Despite being on notice of misconduct, they have continued to pursue off-label marketing and kickbacks as part of their core business strategy.

103. Retaliatory actions were often taken against those individuals who spoke out. For example, over the past 4 months alone, at least 4 members of the MSL organization have resigned, or been forced to resign, in retaliation for their expressing concerns about fraudulent conduct and business activities.

LEGAL CLAIMS FOR RELIEF

104. Relators allege that Defendants' conduct detailed above violates the False Claims Act ("FCA") of the United States, 31 U.S.C. §§ 3729-3733, as amended (Counts One through Four), and the False Claims Acts of the Plaintiffs States and the District of Columbia (Counts Five through Fifty-Nine). They bring these claims on behalf of the federal and state Plaintiffs as well as on their own behalf.

COUNT ONE

[False and/or Fraudulent Claims, 31 U.S.C. § 3729 (a)(1)]

105. Relators restate and reallege the allegations in paragraphs 1 through 104 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

106. This is a claim for treble damages and monetary penalties pursuant to the False

Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

107. Through the above-described acts and omissions, and from at least on or before 2002 to the present, the Defendants knowingly caused to be presented for payment and approval false and/or fraudulent claims to officers of the United States Government, in that they caused to be presented claims to obtain reimbursement for the drugs when the Defendants knew such items were not eligible for reimbursement or not eligible in part. Prescriptions for these drugs would not have been presented but for the unlawful promotional activities made by Defendants and the kickback activity and resulted in claims which failed to disclose the material violations of the AKA and other laws. As a result of this illegal activity, these claims were improper in whole pursuant to 31 U.S.C. § 3729(a)(1).

108. Federal Health Care Program officials, their contractors, carriers, intermediaries and agents, paid and approved claims for payment for the drugs that should not have been paid or approved.

109. The Defendants, through the means described above, deliberately and intentionally concealed the false and fraudulent nature of the claims from officials with Government Health Care Programs, and other Government officials, their contractors, carriers, intermediaries and agents, in order to induce payment of the false and fraudulent claims.

110. Government Health Care Program officials and their contractors, carriers, intermediaries and agents, would not have paid the claims for the drugs had they known the truth.

111. By reason of the above-described presentment of false and fraudulent claims, the United States has suffered significant losses in an amount to be determined.

COUNT TWO

[False Records and Statements, 31 U.S.C. § 3729 (a)(2)]

112. Relators restate and reallege the allegations in paragraphs 1 through 111 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

113. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

114. Through the above-described acts and omissions, and from on or before at least 2002 to the present, the Defendants knowingly made and used, and caused to be made and used, false records and statements for the purpose of having false and fraudulent claims for the drugs paid and approved by Federal Health Care Program officials, their contractors, carriers, intermediaries and agents. Such prescriptions would not have been presented but for the unlawful promotional activities made by Defendants and the kickback activity. As a result of this illegal activity, these claims were improper in whole pursuant to 31 U.S.C. § 3729(a)(2).

115. By reason of the above-described presentment of false records and statements, the United States has suffered significant losses in an amount to be determined.

COUNT THREE

[Conspiracy to Defraud, 31 U.S.C. § 3729 (a)(3)]

116. Relators restate and reallege the allegations in paragraphs 1 through 115 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

117. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

118. Through the above-described acts and omissions, and from on or before at least 2002 to the present, the Defendants, with each other and with persons known and unknown, knowingly agreed and conspired to defraud the federal and state governments by having false and fraudulent claims for the drugs paid and approved by Federal Health Care Program officials, their contractors, carriers, intermediaries and agents. Such prescriptions would not have been presented but for the unlawful promotional activities made by Defendants and the kickback activity. As a result of this illegal activity, these claims were improper in whole pursuant to 31 U.S.C. § 3729(a)(1)-(2).

119. By reason of the above-described unlawful conspiracy, the United States has suffered significant losses in an amount to be determined.

COUNT FOUR

[False Statements to Conceal Obligations, 31 U.S.C. § 3729(a)(7)]

120. Relators restate and reallege the allegations in paragraphs 1 through 119 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

121. This is a claim for treble damages and monetary penalties pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, as amended.

122. Through the above-described acts and omissions, the Defendants knowingly made and used, and/or caused to be made and used, false records and statements regarding the drugs in order to conceal, avoid and/or decrease the Defendants' obligations to pay or transmit rebate monies or to offer certain prices to Government Health Care Programs to the United States. In addition, these claims were monetarily excessive because they were improperly inflated by Defendants' illegal marketing and promotional activities. Claims to Government Health Care

Programs as described above were false or fraudulent and the statements and records were false because they were monetarily excessive.

123. By reason of the above-described false records and statements, the United States has suffered significant losses in an amount to be determined.

COUNT FIVE

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)(1)

124. Relators restate and reallege the allegations in paragraphs 1 through 123 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

125. The California False Claims Act, Cal. Gov't Code § 12651(a)(1), specifically provides, in part:

> (a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state . . . for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:
>
> (1) Knowingly presents or causes to be presented to an officer or employee of the state . . . a false claim for payment or approval.

126. Defendants knowingly presented or caused to be presented to the California Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Cal. Gov't Code

§ 12651(a)(1).

127. The State of California paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SIX

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)(2)

128. Relators restate and reallege the allegations in paragraphs 1 through 127 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

129. The California False Claims Act, Cal. Gov't Code § 12651(a)(2), specifically provides:

> (a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state... for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:
>
> (2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state . . . .

130. Defendants knowingly made, used and/or caused to be made or used false records and statements to get false and fraudulent claims paid and approved by the California Medicaid program, in violation of Cal. Gov't Code § 12651(a)(2).

131. The State of California paid said claims and has sustained damages because of

these acts by the Defendants.

COUNT SEVEN

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)(3)

132. Relators restate and reallege the allegations in paragraphs 1 through 131 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

133. The California False Claims Act, Cal. Gov't Code § 12651(a)(3), specifically provides:

> (a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state . . . for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:
>
> (3) Conspires to defraud the state . . . by getting a false claim allowed or paid by the state . . .

134. Defendants conspired to defraud the State of California by getting false and fraudulent claims allowed and paid, in violation of Cal. Gov't Code § 12651(a)(3).

135. The State of California paid said claims and has sustained damages because of these acts by the Defendants.

COUNT EIGHT

VIOLATIONS OF THE CALIFORNIA FCA
Cal. Gov't Code § 12651(a)(7)

136. Relators restate and reallege the allegations in paragraphs 1 through 135 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

137. The California False Claims Act, Cal. Gov't Code § 12651(a)(7), specifically provides:

> (a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state . . . for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand ($10,000) for each false claim:
>
> (7) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state . . . .

138. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Cal. Gov't Code § 12651(a)(7).

139. The State of California paid said claims and has sustained damages because of these acts by the Defendants.

COUNT NINE

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT
Del. Code Ann. tit. 6, § 1201(a)(1)

140. Relators restate and reallege the allegations in paragraphs 1 through 139 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

141. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(1), specifically provides, in part, that any person who:

(a)(1) Knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;

shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

142. Defendants knowingly presented or caused to be presented, directly and indirectly, to the Delaware Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Del. Code Ann. tit. 6, § 1201(a)(1).

143. The State of Delaware paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TEN

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT
Del. Code Ann. tit. 6, § 1201(a)(2)

144. Relators restate and reallege the allegations in paragraphs 1 through 143 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

145. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(2), specifically provides, in part, that any person who:

> (a)(2) Knowingly makes, uses or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved;
>
> shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

146. Defendants knowingly made, used and caused to be made and used, directly and indirectly, false records and statements to get false and fraudulent claims paid and approved by the State of Delaware, in violation of Del. Code Ann. tit. 6, § 1201(a)(2).

147. The State of Delaware paid said claims and has sustained damages because of these acts by the Defendants.

COUNT ELEVEN

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT Del. Code Ann. tit. 6, § 1201(a)(3)

148. Relators restate and reallege the allegations in paragraphs 1 through 147 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

149. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(3), specifically provides, in part, that any person who:

> (a)(3) Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section,

plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

150. Defendants conspired to defraud the State of Delaware by getting false and fraudulent claims allowed and paid, in violation of Del. Code Ann. tit. 6, § 1201(a)(3).

151. The State of Delaware paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWELVE

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT Del. Code Ann. tit. 6, § 1201(a)(7)

152. Relators restate and reallege the allegations in paragraphs 1 through 151 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

153. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(7), specifically provides, in part, that any person who:

> (a)(7) Knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, increase, or decrease an obligation to pay or transmit money to or from the government; shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

154. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Del. Code Ann. tit. 6, § 1201(a)(7).

155. The State of Delaware paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTEEN

VIOLATIONS OF THE DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code § 2-308.14(a)(1)

156. Relators restate and reallege the allegations in paragraphs 1 through 155 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

157. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(1), specifically provides, in part:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
>
> (1) Knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval.

158. Defendants knowingly caused to be presented to the District of Columbia Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of D.C. Code § 2-308.14(a)(1).

159. The District of Columbia paid said claims and has sustained damages because of

these acts by the Defendants.

COUNT FOURTEEN

VIOLATIONS OF THE DISTRICT OF THE COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code § 2-308.14(a)(2)

160. Relators restate and reallege the allegations in paragraphs 1 through 159 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

161. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(2), specifically provides, in part:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;

162. Defendants knowingly made, used and caused to be made and used, directly and indirectly, false records and statements to get false and fraudulent claims paid and approved by the District of Columbia, in violation of D.C. Code § 2-308.14(a)(2).

163. The District of Columbia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTEEN

VIOLATIONS OF THE DISTRICT OF THE COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code § 2-308.14(a)(3)

164. Relators restate and reallege the allegations in paragraphs 1 through 163 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

165. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(3), specifically provides:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
>
> (3) Conspires to defraud the District by getting a false claim allowed or paid by the District;

166. Defendants conspired to defraud the District of Columbia by getting false and fraudulent claims allowed and paid, in violation of D.C. Code § 2-308.14(a)(3).

167. The District of Columbia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SIXTEEN

VIOLATIONS OF THE DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT D.C. Code § 2-308.14(a)(7)

168. Relators restate and reallege the allegations in paragraphs 1 through 167 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

169. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(7), specifically provides, in part:

> (a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than $5,000, and not more than $10,000, for each false claim for which the person:
>
> (7) Knowingly makes uses or causes to be made or used a false record or statement to conceal, avoid, increase, or decrease an obligation to pay or transmit money to or from the government;

170. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of D.C. Code § 2-308.14(a)(7).

171. The District of Columbia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT SEVENTEEN

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)(a)

172. Relators restate and reallege the allegations in paragraphs 1 through 171 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

173. The Florida False Claims Act, Fla. Stat. § 68.082(2)(a), specifically provides, in part, that any person who:

> (a) Knowingly presents or causes to be presented to an officer or employee of an agency a false claim for payment or approval; ...is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

174. Defendants knowingly presented or caused to be presented to the Florida Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Fla. Stat. § 68.082(2)(a).

175. The State of Florida paid said claims and has sustained damages because of these acts by the Defendants.

COUNT EIGHTEEN

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)(b)

176. Relators restate and reallege the allegations in paragraphs 1 through 175 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

177. The Florida False Claims Act, Fla. Stat. § 68.082(2)(b), specifically provides, in

part, that any person who:

(b) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by an agency; ...

is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

178. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by an agency of the State of Florida, in violation of Fla. Stat. § 68.082(2)(b).

179. The State of Florida paid said claims and has sustained damages because of these acts by the Defendants.

COUNT NINETEEN

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)(c)

180. Relators restate and reallege the allegations in paragraphs 1 through 179 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

181. The Florida False Claims Act, Fla. Stat. § 68.082(2)(c), specifically provides, in part, that any person who:

(c) Conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid;. . .is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

182. Defendants conspired to submit a false claim to Government Health Care Programs and to deceive Federal/Government Health Care Programs for the purpose of getting false and fraudulent claims allowed and paid, in violation of Fla. Stat. § 680.82(2)(c).

183. The State of Florida paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY

VIOLATIONS OF THE FLORIDA FCA
Fla. Stat. § 68.082(2)(g)

184. Relators restate and reallege the allegations in paragraphs 1 through 183 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

185. The Florida False Claims Act, Fla. Stat. § 68.082(2)(g), specifically provides, in part, that any person who:

> (g) Knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to an agency. . .is liable to the state for a civil penalty of not less than $5,000 and not more than $10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

186. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Fla. Stat. § 680.82(2)(g).

187. The State of Florida paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-ONE

VIOLATIONS OF THE GEORGIA STATE FALSE MEDICAID CLAIMS ACT

Article 7B, Chapter 4, Title 49 of the Official Code of Georgia Annotated

188. Relators restate and reallege the allegations contained in Paragraphs 1 through 187 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

189. The Georgia State False Medicaid Claims Act, Official Code of Georgia Annotated, 49-4-168, *et seq*., specifically provides, in part at 49-4-168.1, that:

> (a) Any person who:
>
> (1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;
> (3) Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid;
> (4) Has possession, custody, or control of property or money used, or to be used by the Georgia Medicaid program and, intending to defraud the Georgia Medicaid program or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate of receipt…or
> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay, repay or transmit money or property to the State of Georgia,
> shall be liable to the State of Georgia for a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each false or fraudulent claim, plus three times the amount of damages which the Georgia Medicaid program sustains because of the act of such person.

190. The Defendants knowingly presented or caused to be presented false or fraudulent claims to Medicaid and knowingly made, used or caused to be made or used, false statements to get said claims paid by the Medicaid Programs. Prescriptions for the purposes of off-label uses would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendants. As a result of this illegal scheme, these claims were improper in whole

pursuant to the Georgia FCA, 49-4-168.1(a)(1)-(2).

191. These claims were also false or fraudulent and the statements and records were false because they were monetarily excessive. Prescriptions for the purposes of off-label uses cost more than comparative drugs with the same or superior efficacy.

192. In particular, these claims were also false or fraudulent and statements and records were false because the cost to the Government Healthcare Programs was inflated due to the Defendants having to cover their illegal expenditures and unlawful promotional activities, thereby inflating the cost of the product.

193. It is illegal to pass the costs of illegal kickbacks and unlawful promotional activities back to any Federal or Government Health Care Program and it is also illegal to falsely report the true cost of a drug. In addition to violating 49-4-168.1(a)(1)-(2), Defendants' conduct violated 49-4-168.1(a)(4) and (7).

194. Defendants knowingly conspired to defraud the State of Georgia causing increased sales through unlawful promotion and kickbacks in violation of law. Defendants conspired to violate the AKA by unlawfully offering incentives to physicians that were in a position of authority to cause other physicians to write unnecessary prescriptions. Said actions constitute violations of 49-4-168.1(a)(3).

195. Defendants knowingly conspired to violate the Georgia FCA by causing false or fraudulent claims to be presented and to make or use false statements which damaged the Medicaid Program. Said claims were improper and should not have been made but for the unlawful promotional activities and unlawful incentives. Said claims were also monetarily excessive in cost due to the illegal kickbacks and unlawful promotional activities of the Defendants. Said actions constitute violations of 49-4-168.1(a)(3).

196. The Defendants knowingly conspired to conceal their actions and they failed to alert the state or federal governments of their unlawful promotional activities. It is illegal to pass the costs incurred in paying illegal kickbacks and unlawful promotional activities back to any Federal or Government Health Care Program and it is also illegal to falsely report the true cost of a drug. Said actions constitute violations of 49-4-168.1(a)(3).

197. Defendants knowingly presented or caused to be presented to the Georgia Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of 49-4-168.1(a)(1)-(4) and (7).

198. The State of Georgia paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Georgia, because of these acts by the Defendants.

COUNT TWENTY-TWO

VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21(a)(1)

199. Relators restate and reallege the allegations in paragraphs 1 through 198 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

200. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(1), specifically provides, in part, that any person who:

(1) Knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;

. . .

shall be liable to the State for a civil penalty of not less than $5,000 and not more than

$10,000, plus three times the amount of damages that the State sustains due to the act of that person.

201. Defendants knowingly presented or caused to be presented to the Hawaii Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Haw. Rev. Stat. § 661-21(a)(1).

202. The State of Hawaii paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-THREE
VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21(a)(2)

203. Relators restate and reallege the allegations in paragraphs 1 through 202 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

204. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(2), specifically provides, in part, that any person who:

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

. . .

shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

205. Defendants knowingly made, used and caused to be made, used, and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved

by the State of Hawaii, in violation of Haw. Rev. Stat. § 661-21(a)(2).

206. The State of Hawaii paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-FOUR

VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21(a)(3)

207. Relators restate and reallege the allegations in paragraphs 1 through 206 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

208. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(3), specifically provides, in part, that any person who:

> (3) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid.
>
> . . .
>
> shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

209. Defendants conspired to defraud the State of Hawaii by getting false and fraudulent claims allowed and paid, in violation of Haw. Rev. Stat. § 661-21(a)(3).

210. The State of Hawaii paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-FIVE

VIOLATIONS OF THE HAWAII FCA
Haw. Rev. Stat. § 661-21(a)(7)

211. Relators restate and reallege the allegations in paragraphs 1 through 210 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

212. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(7), specifically provides, in part, that any person who:

> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state.
>
> . . .
>
> shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the State sustains due to the act of that person.

213. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Haw. Rev. Stat. § 661-21(a)(7).

214. The State of Hawaii paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-SIX

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWERREWARD AND PROTECTION ACT 740 Ill. Comp. Stat. § 175/3 (a)(1)

215. Relators restate and reallege the allegations in paragraphs 1 through 214 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

216. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(1), specifically provides, in part, that any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the State or member of the Guard a false or fraudulent claim for payment or approval;
>
> . . .
>
> is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

217. Defendants knowingly caused to be presented to the Illinois Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of 740 Ill. Comp. Stat. § 175/3(a)(1).

218. The State of Illinois paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-SEVEN

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT 740 Ill. Comp. Stat. § 175/3(a)(2)

219. Relators restate and reallege the allegations in paragraphs 1 through 218 above as

if each were stated herein in their entirety and said allegations are incorporated herein by reference.

220. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(2), specifically provides, in part, that any person who:

> (2) knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
>
> . . .
>
> is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

221. Defendants knowingly made, used and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the State of Illinois, in violation of 740 Ill. Comp. Stat. § 175/3(a)(2).

222. The State of Illinois paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-EIGHT

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT 740 Ill. Comp. Stat. § 175/3(a)(3)

223. Relators restate and reallege the allegations in paragraphs 1 through 222 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

224. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(3), specifically provides, in part, that any person who:

(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid;

. . .

is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

225. Defendants conspired to defraud the State of Illinois by getting false and fraudulent claims allowed and paid, in violation of 740 Ill. Comp. Stat. § 175/3(a)(3).

226. The State of Illinois paid said claims and has sustained damages because of these acts by the Defendants.

COUNT TWENTY-NINE

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT 740 Ill. Comp. Stat. § 175/3(a)(7)

227. Relators restate and reallege the allegations in paragraphs 1 through 226 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

228. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3(a)(7), specifically provides, in part, that any person who:

(7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the State

. . .

is liable to the State for a civil penalty of not less than $5,000 and not more than $10,000,

plus 3 times the amount of damages which the State sustains because of the act of that person.

229. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of 740 Ill. Comp. Stat. § 175/3(a)(7).

230. The State of Illinois paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY

VIOLATIONS OF THE STATE OF INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT IC 5-11-5.5

231. Relators restate and reallege the allegations in paragraphs 1 through 230 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

232. The Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5-2(b) (2005), specifically provides, in part, that by certain acts a person commits an unlawful act and shall be liable to the state for civil penalties and three times the amount of damages that the state sustains because of the act of that person [including]:

> (1) presents a false claim to the state for payment or approval;
> (2) makes or uses a false record or statement to obtain payment or approval of a false claims from the state;...
> (6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;
> (7) conspires with another person to perform an act described above; or
> (8) causes or induces another person to perform an act described above.

233. Defendants knowingly violated these provisions of law by presenting or causing to be presented to the Indiana Medicaid program false and/or fraudulent claims for payment and

approval, claims which failed to disclose the material violations of the law; knowingly made, used or caused to be made or used a false record or statement to support such claims and/or to conceal its actions and to avoid or decrease an obligation to pay or transmit money to the state, and conspired to defraud the state Medicaid program, and caused others to violate the Indiana Act, all in violation of IC 5-11-5.5-2.

234. The State of Indiana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-ONE

VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
46 La. Rev. Stat. c. 3 § 438.3A

235. Relators restate and reallege the allegations in paragraphs 1 through 234 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

236. The Louisiana False Claims Act/Medical Assistance Programs Integrity Law ("Louisiana FCA"), 46 La. Rev. Stat. c. 3 § 438.3A, specifically provides, in part, that: "No person shall knowingly present or cause to be presented a false or fraudulent claim".

237. Defendants knowingly presented or caused to be presented to the Louisiana Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of 46 La. Rev. Stat. c. 3 § 438.3A.

238. The State of Louisiana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-TWO
VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
46 La. Rev. Stat. c. 3 § 438.3B

239. Relators restate and reallege the allegations in paragraphs 1 through 238 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

240. The Louisiana FCA, 46 La. Rev. Stat. c. 3 § 438.3B, specifically provides, in part, that:

> No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance programs funds.

241. Defendants knowingly engaged in misrepresentation and made, used and caused to be made and used, false records and statements to obtain or attempt to obtain payment from or get false and fraudulent claims paid and approved by the State of Illinois, in violation of 46 La. Rev. Stat. c. 3 § 438.3B.

242. The State of Louisiana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-THREE

VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
46 La. Rev. Stat. c. 3 § 438.3C

243. Relators restate and reallege the allegations in paragraphs 1 through 242 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

244. The Louisiana FCA, 46 La. Rev. Stat. c. 3 § 438.3C, specifically provides, in part,

that:

> No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

245. Defendants conspired to defraud the State of Louisiana by getting false and fraudulent claims allowed and paid, in violation of 46 La. Rev. Stat. c. 3 § 438.3C.

246. The State of Louisiana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-FOUR

VIOLATIONS OF THE LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
46 La. Rev. Stat. c. 3 § 438.2A(1)

247. Relators restate and reallege the allegations in paragraphs 1 through 246 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

248. Louisiana FCA, 46 La. Rev. Stat. c. 3 § 438.2A(1), specifically provides that:

> No person shall solicit, receive, offer or pay any remuneration, including but not limited to kickbacks, bribes, rebates, or … payments, directly or indirectly, overtly or covertly, in cash or in kind, for the following . ..
>
> (1) In return for referring an individual to a health care provider, …for the furnishing or arranging to furnish any good, supply, or service for which payment may be made, in whole or in part, under the medical assistance programs.

249. In addition, the Louisiana FCA, supra, section 438.3 provides that:

> "No person shall knowingly present of cause to be presented a false or fraudulent

claim…shall knowingly engage in misrepresentation to obtain, or attempt to obtain payment from medical assistance program funds…shall conspire to defraud, or attempt to defraud, the medical assistance programs… ."

250. Furthermore, the Louisiana FCA, supra, section 438.4 provides that:

"No person shall knowingly make, use or cause to be made or used a false, fictitious, or misleading statement on any form used for the purpose of certifying or qualifying any person for eligibility … to receive any good, service, or supply under the medical assistance programs which that person is not eligible to receive."

251. Defendants solicited, received, offered and/or paid remuneration, including but not limited to kickbacks, bribes, and gifts, directly or indirectly, overtly or covertly, in cash or in kind, in return for prescribing or arranging the prescribing of drugs which are paid for by the Louisiana Medicaid program, in violation of 46 La. Rev. Stat. c. 3 § 438.2A(1).

252. The State of Louisiana paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-FIVE

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(1)

253. Relators restate and reallege the allegations in paragraphs 1 through 258 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

254. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(1), specifically provides, in part, that any person who:

(1) knowingly presents, or causes to be presented, a false or fraudulent claim for

payment or approval;

. . .

shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

255. Defendants knowingly presented or caused to be presented to the Massachusetts Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Mass. Gen. Laws Ch. 12, § 5B(1).

256. The Commonwealth of Massachusetts paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-SIX

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(2)

257. Relators restate and reallege the allegations in paragraphs 1 through 262 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

258. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(2), specifically provides, in part, that any person who:

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof;

. . .

shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

258. Defendants knowingly made, used and caused to be made and used, false records and statements to obtain payment and approval of claim by the Commonwealth of Massachusetts, in violation of Mass. Gen. Laws Ch. 12, § 5B(2).

260. The Commonwealth of Massachusetts paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-SEVEN

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(3)

261. Relators restate and reallege the allegations in paragraphs 1 through 260 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

262. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(3), specifically provides, in part, that any person who:

(3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;

. . .

shall be liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

263. Defendants conspired to defraud the Commonwealth of Massachusetts through the allowance and payment of fraudulent claims in violation of Mass. Gen. Laws Ch. 12, § 5B(3).

264. The Commonwealth of Massachusetts paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-EIGHT

VIOLATIONS OF THE MASSACHUSETTS FCA
Mass. Gen. Laws Ch. 12, § 5B(8)

265. Relators restate and reallege the allegations in paragraphs 1 through 264 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

266. The Massachusetts False Claims Act, Mass. Gen. Laws Ch. 12, § 5B(8), specifically provides, in part, that any person who:

(8) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or to transmit money or property to the commonwealth;

. . .

shall be liable to the commonwealth or political subdivision for a civil penalty of not less

than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

267. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Mass. Gen. Laws Ch. 12, § 5B(8).

268. The Commonwealth of Massachusetts paid said claims and has sustained damages because of these acts by the Defendants.

COUNT THIRTY-NINE

VIOLATIONS OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT, MI ST Ch. 400

269. Relators restate and reallege the allegations in paragraphs 1 through 268 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

270. The Michigan Medicaid False Claims Act, MI ST Ch. 400, provides, *inter alia*: as follows:

(1) In section 400.603, that "A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for Medicaid benefits… [or] for use in determining rights to a Medicaid benefit." It further provides that "A person, having knowledge of the occurrence of an event affecting …[the] initial or continued right of any other person on whose behalf he has applied…shall not conceal or fail to disclose that event with intent to obtain a benefit to which the person or any other person is not entitled or in an amount greater than that to which the person or any other person is entitled."

(2) In section 400.606, that "A person shall not enter into an agreement,

combination, or conspiracy to defraud the state by obtaining or aiding another to obtain the payment or allowance of a false claim... ."

(3) In section 400.607, that "A person shall not make or present or cause to be made or presented to an employee or officer [of the state] a claim...upon or against the state, knowing the claim to be false... ." and that " A person shall not make or present or cause to be made or presented a claim ...which he or she knows falsely represents that the goods or services for which the claim is made were medically necessary ... ."

(4) In section 400.604, that a person is prohibited from soliciting, offering, making or receiving a kickback or bribe or rebate of any kind.

271. Under section 400.612, "A person who receives a benefit which the person is not entitled to receive by reason of fraud or making a fraudulent statement or knowingly concealing a material fact shall forfeit and pay to the state a civil penalty equal to the full amount received plus triple the amount of damages suffered by the state as a result of the conduct by the person".

272. Defendants have violated these provisions of the Michigan FCA and caused damage to the State of Michigan.

COUNT FORTY

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. § 357.040(1)(a)

273. Relators restate and reallege the allegations in paragraphs 1 through 272 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

274. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(a), specifically provides, in part, that a person who:

With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $2,000 or more than $10,000 for each act:

(a) Knowingly presents or causes to be presented a false claim for payment or approval.

275. Defendants knowingly presented or caused to be presented to the Nevada Medicaid program false claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Nev. Rev. Stat. § 357.040(1)(a).

276. The State of Nevada paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-ONE

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. § 357.040(1)(b)

277. Relators restate and reallege the allegations in paragraphs 1 through 282 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

278. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(b), specifically provides, in part, that a person who:

With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of

not less than $2,000 or more than $10,000 for each act:

. . .

(b) Knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim.

279. Defendants knowingly made, used and caused to be made and used, false records and statements to obtain payment and approval of false claims, in violation of Nev. Rev. Stat. § 357.040(1)(b).

280. The State of Nevada paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-TWO

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. 357.040(1)(c)

281. Relators restate and reallege the allegations in paragraphs 1 through 280 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

282. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(c), specifically provides, in part, that a person who:

With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $2,000 or more than $10,000 for each act:

. . .

(c) Conspires to defraud by obtaining allowance or payment of a false claim.

283. Defendants conspired to defraud the State of Nevada by obtaining allowance and payment of false claims, in violation of Nev. Rev. Stat. 357.040(1)(c).

284. The State of Nevada paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-THREE

VIOLATIONS OF THE NEVADA FCA
Nev. Rev. Stat. 357.040(1)(g)

285. Relators restate and reallege the allegations in paragraphs 1 through 284 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

286. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(g), specifically provides, in part, that a person who:

> With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than $2,000 or more than $10,000 for each act:
>
> . . .
>
> (g) knowingly makes or uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state....

287. Defendants knowingly made, used or caused to be made or used a false record or

statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Nev. Rev. Stat. 357.040(1)(g).

288. The State of Nevada paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-FOUR

VIOLATIONS OF THE NEW HAMPSHIRE FCA
N.H. RSA §§ 167:61-b *et seq.*

289. Relators restate and reallege the allegations in paragraphs 1 through 288 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

290. The New Hampshire Medicaid False Claims Act, N.H. RSA §§ 167:61-b *et seq.* (2005), specifically provides, in part, that by certain acts a person commits an unlawful act and shall be liable to the state for a civil penalty and three times the amount of damages that the state sustains because of the act if that person:

> (a) presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent claim;
>
> (b) makes, uses or causes to be made or used a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
>
> (c) conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent; [and/or]
>
> (e) makes, uses, or causes to be made or used a record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program, knowing that such record or statement is false...."

291. Defendants knowingly violated these provisions of law by presenting or causing to be presented to the New Hampshire Medicaid program false and/or fraudulent claims for

payment and approval, claims which failed to disclose the material violations of the law; knowingly made, used or caused to be made or used a false record or statement to support such claims and/or to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, and they conspired to defraud the state Medicaid program, all in violation of N.H. RSA § 167:61-b I. (a)-(c) and (e).

292. The State of New Hampshire paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-FIVE

VIOLATIONS OF THE NEW MEXICO FCA
N.M. LEGIS 49 (2004) CHAPTER 4

293. Relators restate and reallege the allegations in paragraphs 1 through 292 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

294. The New Mexico Medicaid False Claims Act, N.M. Legis 49 (2004) Chapter 4, specifically provides, in part, that by certain acts "a person commits an unlawful act and shall be liable to the state for three times the amount of damages that the state sustains because of the act if that person [including]:

4A. presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that such claims is false or fraudulent claim;

4B. presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that the person receiving a Medicaid benefit or payment is not authorized or is not eligible for a benefit under the Medicaid program;

4C. makes, uses or causes to be made or used a record or statement to obtain a false or

fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;

4D. conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent; [and/or]

4E. makes, uses, or causes to be made or used a record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program, knowing that such record or statement is false...."

295. Defendants knowingly violated these provisions of law by presenting or causing to be presented to the New Mexico Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws; they knowingly made, used or caused to be made or used a false record or statement to support such claims and/or to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, and they conspired to defraud the state Medicaid program, all in violation of N.M. Legis 49 (2004) Chapter 4A-E.

296. The State of New Mexico paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-SIX

VIOLATIONS OF THE NEW YORK STATE FCA: 2007 NEW YORK LAWS 58, SECTION 39, ARTICLE XIII, §189 (a)(1),(2) and (7)

297. Relators restate and reallege the allegations contained in Paragraphs 1 to 296 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

298. The Defendants knowingly presented or caused to be presented false or

fraudulent claims to Medicaid and knowingly made, used or caused to be made or used, false statements to get said claims paid by the Medicaid Program. Prescriptions for the purposes of off-label uses would not have been presented but for the illegal incentives and unlawful promotional activities made by Defendants. As a result of this illegal scheme, these claims were improper in whole pursuant to Art. XIII, §189(a)(1).

299. These claims were also false or fraudulent and the statements and records were false because they were monetarily excessive, in violation of Art. XIII, §189 (a)(1)-(2). Prescriptions for the purposes of off-label uses cost more than comparative drugs with the same or superior efficacy.

300. In particular, these claims were also false or fraudulent and statements and records were false because the cost to Government Healthcare Programs was inflated due to the Defendants having to cover their illegal expenditures and unlawful promotional activities, thereby inflating the cost of the product.

301. It is illegal to pass the costs of illegal kickbacks and unlawful promotional activities back to any Federal or Government Health Care Program and it is also illegal to falsely report the true cost of a drug. In addition to violating Art. XIII, §189(a)(1)-(2), Defendants' conduct violated Art. XIII, §189 (a)(7).

COUNT FORTY-SEVEN

CONSPIRACY TO DEFRAUD: NEW YORK FCA, 2007 NEW YORK LAWS 58, SECTION 39, ARTICLE XIII §189 (a)(3)

302. Relators restate and reallege the allegations contained in Paragraphs 1-301 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

303. Defendants knowingly conspired to defraud the State of New York causing increased sales through unlawful promotion in violation of law. Defendants conspired to violate the AKA by unlawfully offering incentives to physicians and offering or receiving incentives from others that were in a position of authority to cause other physicians to write unnecessary prescriptions. Said actions constitute violations of Art.13, Section 189(a)(3).

304. Defendants knowingly conspired to violate the FCA by causing false or fraudulent claims to be presented and to make or use false statements which damaged the Medicaid Program. Said claims were improper and should not have been made but for the unlawful promotional activities and unlawful incentives. Said claims were also monetarily excessive in cost due to the illegal kickbacks and unlawful promotional activities of the Defendants. Said actions constitute violations of Art. XIII, Section 189(a)(3).

305. The Defendants knowingly conspired to conceal their actions and they failed to alert the state or federal governments of their unlawful promotional activities. It is illegal to pass the costs incurred in paying illegal kickbacks and unlawful promotional activities back to any Federal or Government Health Care Program and it is also illegal to falsely report the true cost of a drug. Said actions constitute violations of Art XIII, Section 189(a)(3).

COUNT FORTY-EIGHT

VIOLATIONS OF THE TENNESSEE MEDICAID FCA
Tenn. Code Ann. § 71-5-182(a)(1)(A)

306. Relators restate and reallege the allegations in paragraphs 1 through 311 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

307. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(A), specifically provides, in part, that any person who:

> (A) Presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing such claim is false or fraudulent;
>
> . . .
>
> is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

308. Defendants knowingly presented or caused to be presented to the Tennessee Medicaid program claims for payment under the Medicaid program knowing such claims were false and fraudulent, claims which failed to disclose the material violations of the AKA and other laws, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(A).

309. The State of Tennessee paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FORTY-NINE
VIOLATIONS OF THE TENNESSEE MEDICAID FCA
Tenn. Code Ann. § 71-5-182(a)(1)(B)

310. Relators restate and reallege the allegations in paragraphs 1 through 309 above as

if each were stated herein in their entirety and said allegations are incorporated herein by reference.

311. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(B), specifically provides, in part, that any person who:

> (B) Makes, uses, or causes to made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
>
> . . .
>
> is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

312. Defendants made, used and caused to be made and used, records and statements to get false and fraudulent claims under the Medicaid program paid and approved by the State of Tennessee knowing such records and statements were false, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(B).

313. The State of Tennessee paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY

VIOLATIONS OF THE TENNESSEE MEDICAID FCA Tenn. Code Ann. § 71-5-182(a)(1)(C)

314. Relators restate and reallege the allegations in paragraphs 1 through 313 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

315. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(C), specifically provides, in part, that any person who:

> (C) Conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent;
>
> . . .
>
> is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

316. Defendants conspired to defraud the State of Tennessee by getting claims allowed and paid under the Medicaid program knowing such claims were false and fraudulent, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(C).

317. The State of Tennessee paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-ONE

VIOLATIONS OF THE TENNESSEE MEDICAID FCA
Tenn. Code Ann. § 71-5-182(a)(1)(D)

318. Relators restate and reallege the allegations in paragraphs 1 through 323 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

319. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(D), specifically provides, in part, that any person who:

> (D) Makes, uses, or causes to be made or sued, a record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state, relative

to the Medicaid program knowing such record or statement is false;

. . .

is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

320. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(D).

321. The State of Tennessee paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-TWO

VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION LAW
Tex. Hum. Res. Code § 36.002(1)-(2)

322. Relators restate and reallege the allegations in paragraphs 1 through 321 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

323. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001(1), specifically provides, in part, that a person commits an unlawful act if the person:

(1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact:

(A) on an application for a contract, benefit, or payment under the Medicaid program; or

(B) that is intended to be used to determine a person's eligibility for a benefit or

payment under the Medicaid program.

324. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001(2)(B), specifically provides, in part, that a person commits an unlawful act if the person:

(2) knowingly or intentionally conceals or fails to disclose an event: (B) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized… ."

325. Defendants knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the Texas Medicaid program, claims which failed to disclose the material violations of the AKA and other laws, in violation of Tex. Hum. Res. Code § 36.002 (1)-(2).

326. The State of Texas paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Texas, because of these acts by the Defendants.

COUNT FIFTY-THREE

VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION LAW Tex. Hum. Res. Code § 36.002(4)(B)

327. Relators restate and reallege the allegations in paragraphs 1 through 332 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

328. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002(4)(B), specifically provides, in part, that a person commits an unlawful act if the person:

(4) knowingly or intentionally makes, causes to be made, induces, or seeks to induce

the making of a false statement or misrepresentation of material fact concerning:

. . .

(B) Information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

329. Defendants by knowingly and intentionally causing to be made, inducing, and seeking to induce the making of false statements and misrepresentations of material facts concerning information required to be provided by state and federal law, rule, regulation and provider agreements pertaining to the Medicaid program, are in violation of Tex. Hum. Res. Code § 36.002(4)(B).

330. The State of Texas paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-FOUR

VIOLATIONS OF TEXAS MEDICAID FRAUD PREVENTION LAW Tex. Hum. Res. Code § 36.002(5)

331. Relators restate and reallege the allegations in paragraphs 1 through 330 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

332. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002(5), specifically provides, in part, that a person commits an unlawful act if the person:

(5) except as authorized under the Medicaid program, knowingly or intentionally charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service to the

Medicaid recipient is paid for, in whole or in part, under the Medicaid program . . . .

333. Defendants knowingly and intentionally paid and received kickbacks, gifts, money, or other consideration as a condition of service to a Medicaid recipient, in violation of Tex. Hum. Res. Code §36.002(5).

334. The State of Texas paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-FIVE

VIOLATIONS OF TEXAS MEDICAID FRAUD PREVENTION LAW
Tex. Hum. Res. Code § 36.002(9)

335. Relators restate and reallege the allegations in paragraphs 1 through 340 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

336. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002(9), specifically provides, in part, that a person commits an unlawful act if the person:

> (9) knowingly or intentionally enters into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program . . . .

337. Defendants knowingly and intentionally conspired to defraud the State of Texas by aiding another person in obtaining an unauthorized payment from the Medicaid program, in violation of Tex. Hum. Res. Code §36.002(9).

338. The State of Texas paid said claims and has sustained damages, to the extent of its portion of Medicaid losses from Medicaid claims filed in Texas, because of these acts by the Defendants.

COUNT FIFTY-SIX

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT Va. Code Ann. § 8.01-216.3(A)(1)

339. Relators restate and reallege the allegations in paragraphs 1 through 344 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

340. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(1), specifically provides, in part, that any person who:

> 1. Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;
>
> . . .
>
> shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

341. Defendants knowingly presented or caused to be presented, to the Virginia Medicaid program false and fraudulent claims for payment and approval, claims which failed to disclose the material violations of the AKA and other laws, in violation of Va. Code Ann. § 8.01-216.3(A)(1).

342. The Commonwealth of Virginia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-SEVEN

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT Va. Code Ann. § 8.01-216.3(A)(2)

343. Relators restate and reallege the allegations in paragraphs 1 through 348 above as

if each were stated herein in their entirety and said allegations are incorporated herein by reference.

344. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(2), specifically provides, in part, that any person who:

> 2. Knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth;
>
> . . .
>
> shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

345. Defendants knowingly made, used and caused to made and used, false records and statements to get false and fraudulent claims paid and approved by the Commonwealth of Virginia, in violation of Va. Code Ann. §8.01-216.3(A)(2).

346. The Commonwealth of Virginia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-EIGHT

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT Va. Code Ann. § 8.01-216.3(A)(3)

347. Relators restate and reallege the allegations in paragraphs 1 through 346 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

348. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(3), specifically provides, in part, that any person who:

3. Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;

. . .

shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

349. Defendants conspired to defraud the Commonwealth of Virginia by getting false and fraudulent claims allowed and paid, in violation of Va. Code Ann. § 8.01-216.3(A)(3).

350. The Commonwealth of Virginia paid said claims and has sustained damages because of these acts by the Defendants.

COUNT FIFTY-NINE

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT
Va. Code Ann. § 8.01-216.3(A)(7)

351. Relators restate and reallege the allegations in paragraphs 1 through 356 above as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

352. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(7), specifically provides, in part, that any person who:

knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth;

. . .

shall be liable to the Commonwealth for a civil penalty of not less than $5,000 and not

more than $10,000, plus three times the amount of damages sustained by the Commonwealth.

353. Defendants knowingly made, used or caused to be made or used a false record or statement to conceal their actions and to avoid or decrease an obligation to pay or transmit money to the state, in violation of Va. Code Ann.§ 8.01-216.3(A)(7).

354. The Commonwealth of Virginia paid said claims and has sustained damages because of these acts by the Defendants.

PRAYERS FOR RELIEF

WHEREFORE, Relators, acting on behalf of and in the name of the United States of America and the State Plaintiffs, and on their own behalf, demand and pray that judgment be entered as follows against the Defendants as follows:

(a) In favor of the United States against the Defendants jointly and severally for treble the amount of damages to Government Health Care Programs from the illegal marketing, selling, prescribing, pricing and billing alleged herein, plus maximum civil penalties of $11,000.00 for each false claim;

(b) In favor of the United States against the Defendants for disgorgement of the profits earned by Defendants as a result of their illegal schemes;

(c) In favor of the Relators for the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) to include reasonable expenses, attorney fees and costs incurred by Relators;

(d) For all costs of the Federal FCA civil action;

(e) In favor of the Relators and the United States for such other and further relief as this Court deems to be just and equitable;

(f) In favor of the Relators and the named State Plaintiffs against Defendants jointly and severally in an amount equal to three times the amount of damages that California, Delaware, District of Columbia, Florida, Georgia, Hawaii, Indiana, Illinois, Louisiana, Massachusetts, Nevada, New Hampshire, New Mexico, New York, Tennessee, and Virginia have sustained, respectively, as a result of the Defendants' actions, as well as the statutory maximum civil penalty against the Defendants for each violation of each State's FCA;

(g) In favor of the Relators and the Plaintiff State of Texas against Defendants jointly and severally in an amount equal to two times the amount of damages that Texas has sustained as a result of the Defendants' actions, as well as a civil penalty against the Defendants of a statutory maximum for each violation of Tex. Hum. Res. Code § 36.002;

(h) In favor of the Relators and the State of Michigan against the Defendants jointly and severally for a civil penalty equal to one time the loss caused to the Michigan Medicaid program as a result of the Defendants' actions, plus damages equal to three times such loss;

(i) In favor of the Relators for the maximum amount allowed as a Relators' share pursuant to the State FCAs as follows: Cal. Gov't Code 12652(g); Del. Code Ann. Tit. 6, § 1205; D.C. Code § 2-308.14(f); Fla. Stat. § 68.085; Official Code of Georgia Annotated, 49-4-168; Haw. Rev. Stat. § 661-27; 740 Ill. Comp. Stat. § 175/4(d); IC 5-11-5.5; 46 La. Rev. Stat. c. 3, § 437.1 et seq.; Mass. Gen. Laws Ch. 12, § 5F; Nev. Rev. Stat. §§ 357.210, 357.220, MI ST Ch. 400; N.H. RSA §§ 167:61-b; N.M. Legis 49 (2004); Chapter 4, NY laws 58, s. 39, Art. XIII, §189;

Tenn. Code Ann. § 71-5-183(c); Tex. Hum. Res. Code § 36.110, and Va. Code Ann. § 8.01-216.7;

(j) In favor of the Relators for all costs and expenses associated with the supplemental State claims, including attorney's fees and costs; and

(k) In favor of the State Plaintiffs and the Relators for all such other relief as the Court deems just and proper.

PLAINTIFFS/RELATORS DEMAND A TRIAL BY JURY ON ALL COUNTS

Dated: January 8, 2010

Respectfully submitted,

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PLAINTIFFS/RELATORS DEMAND A TRIAL BY JURY ON ALL COUNTS

Dated: January 8, 2010

Respectfully submitted,

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